

FIGURE 1

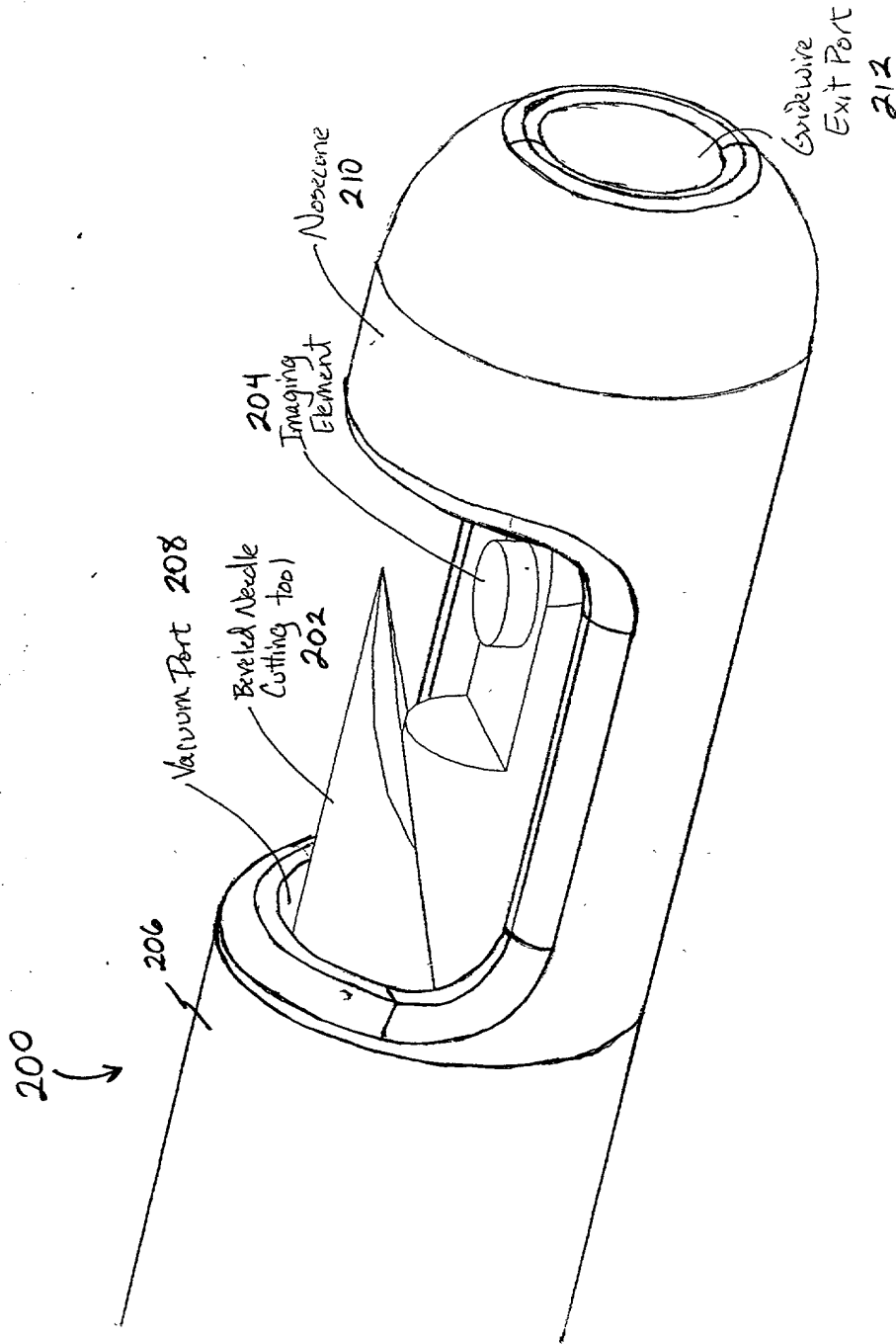


FIGURE 2

300  
↓

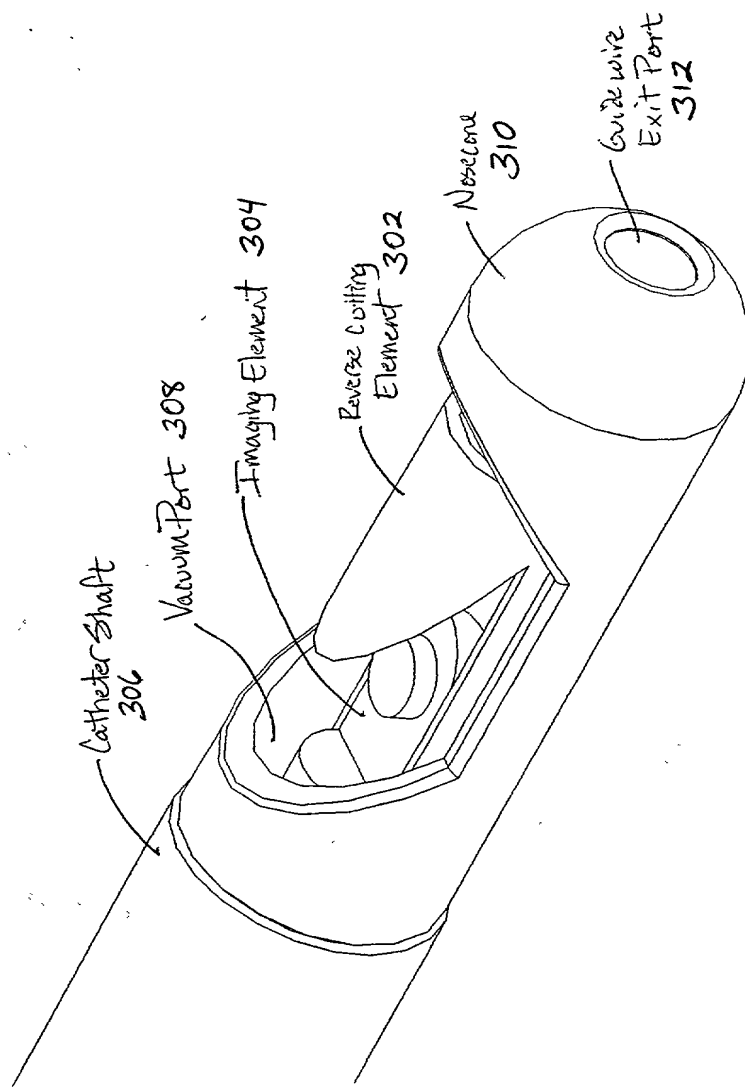


FIGURE 3

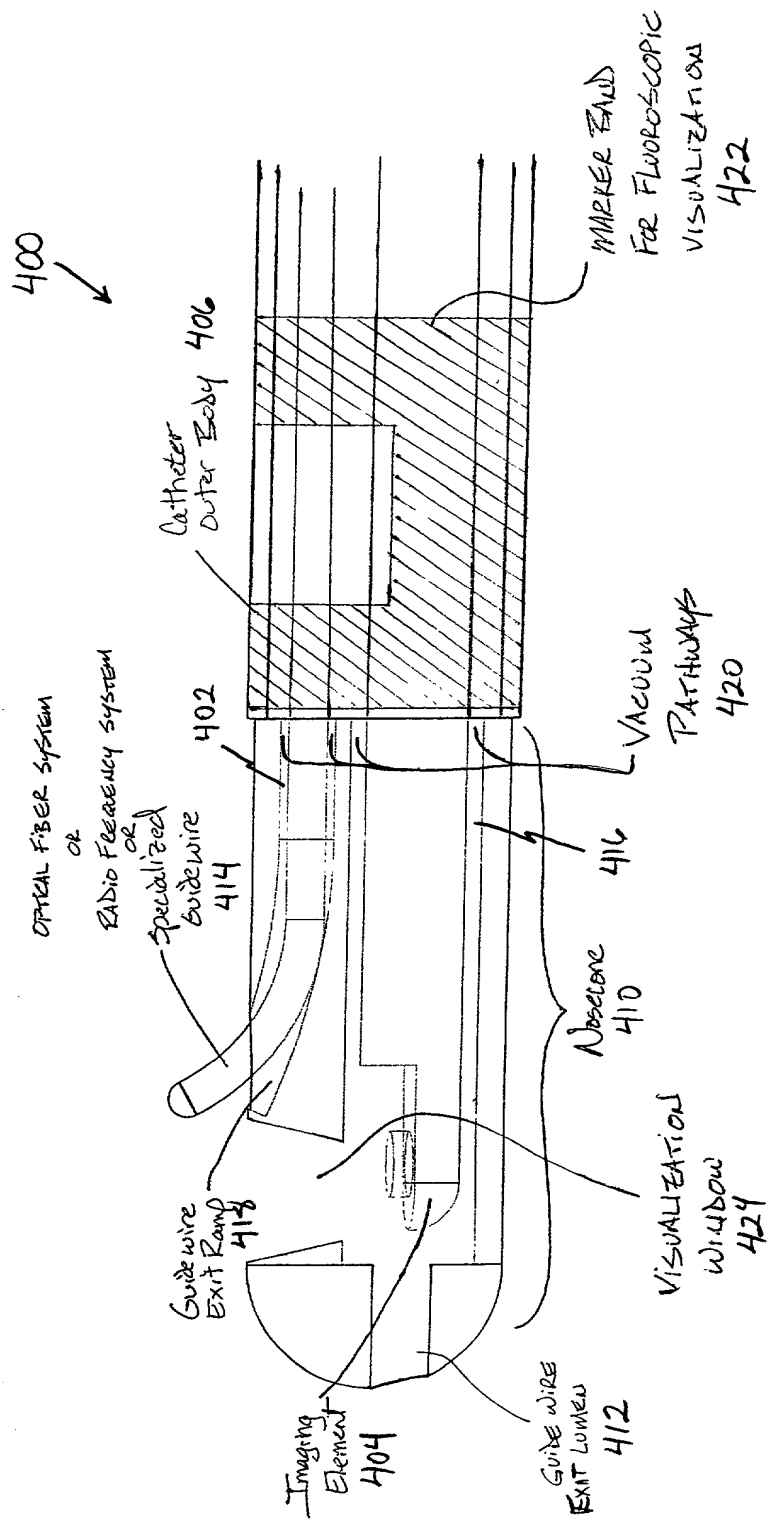


FIGURE 4

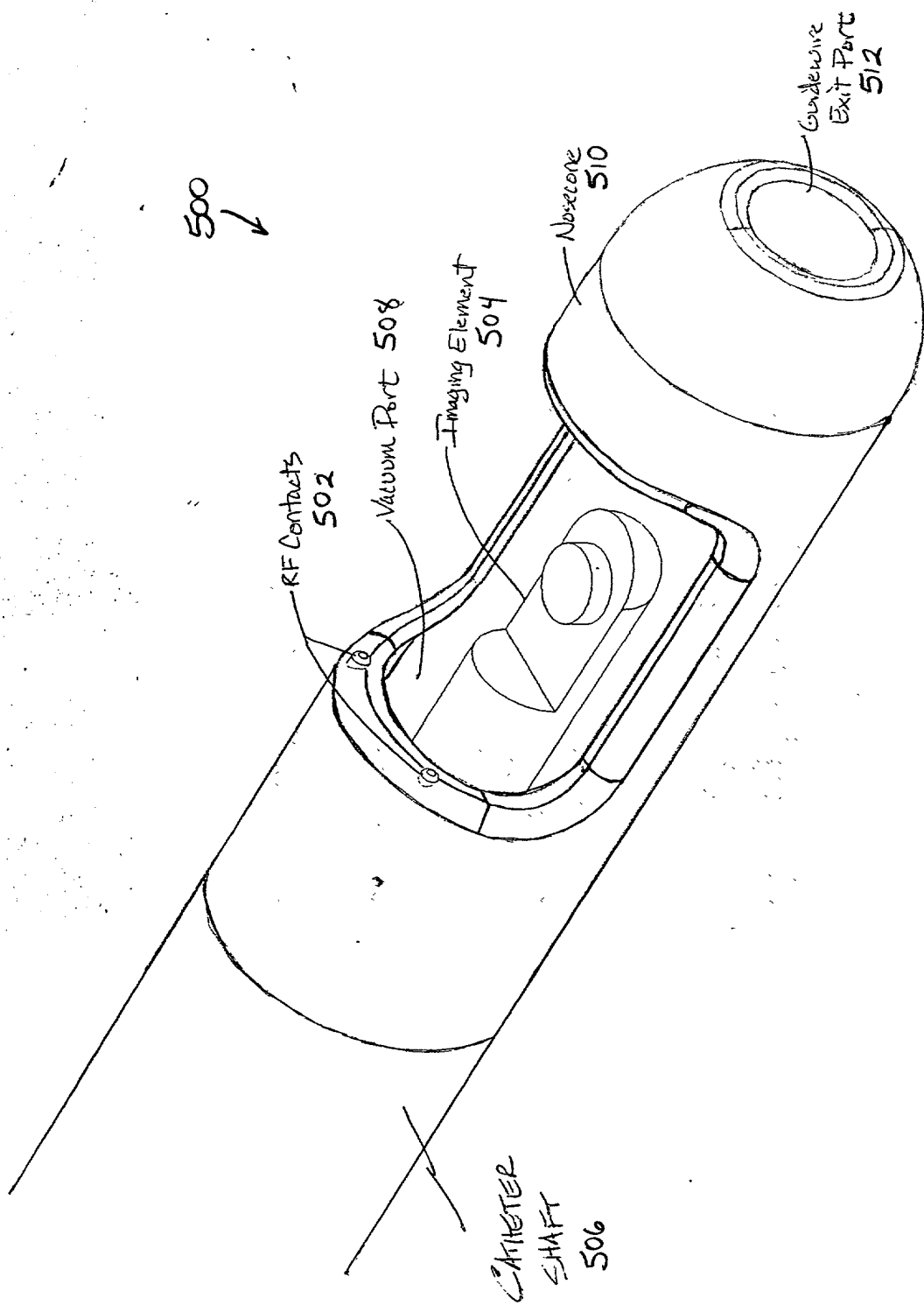


FIGURE 5

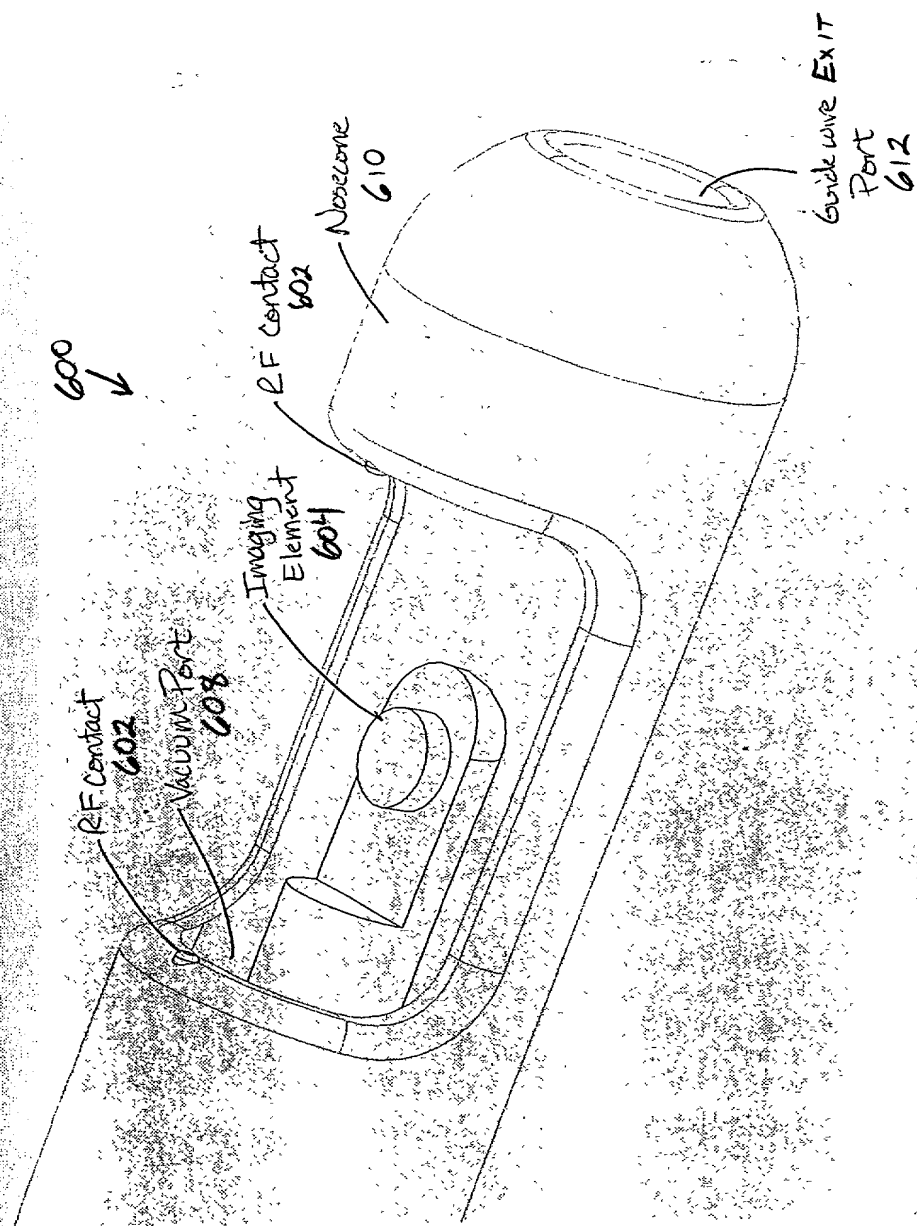


FIGURE 6

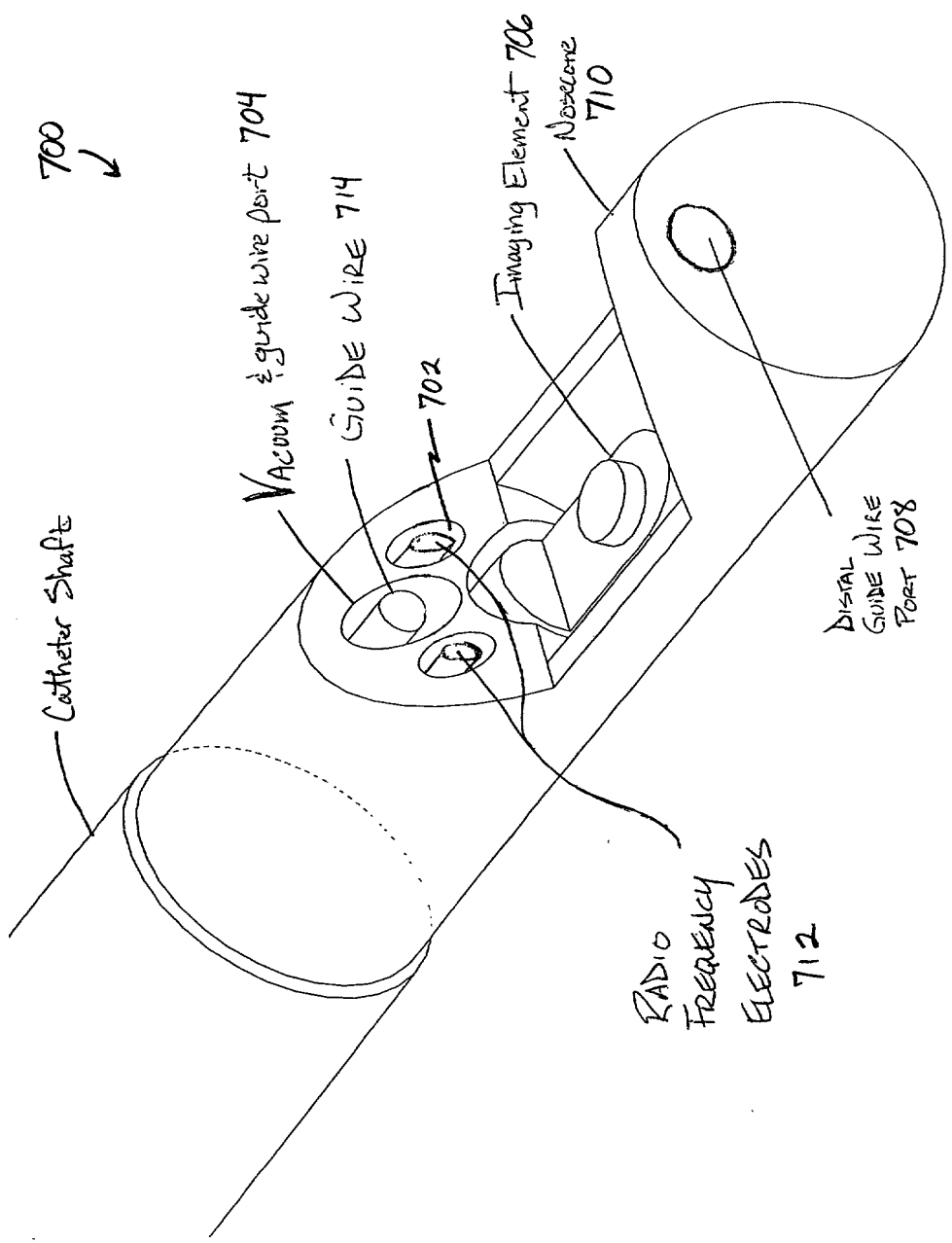


FIGURE 7A





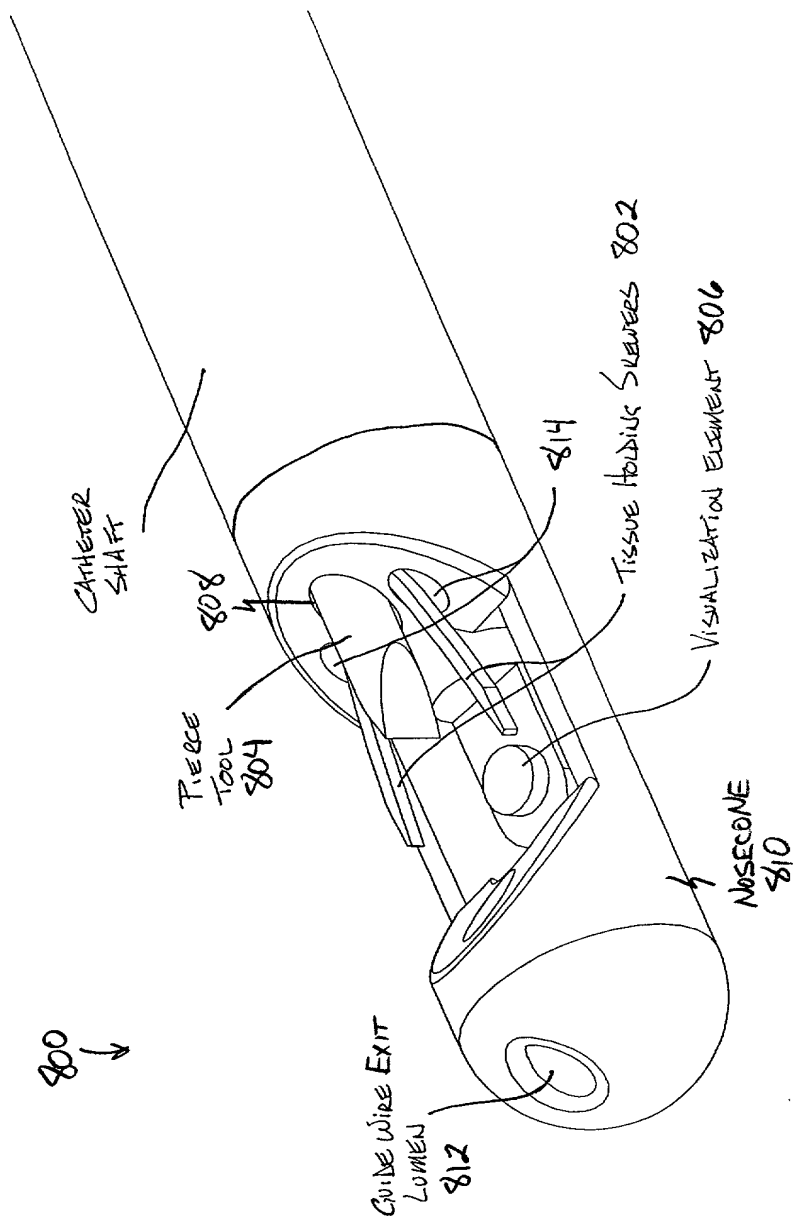


FIGURE 8

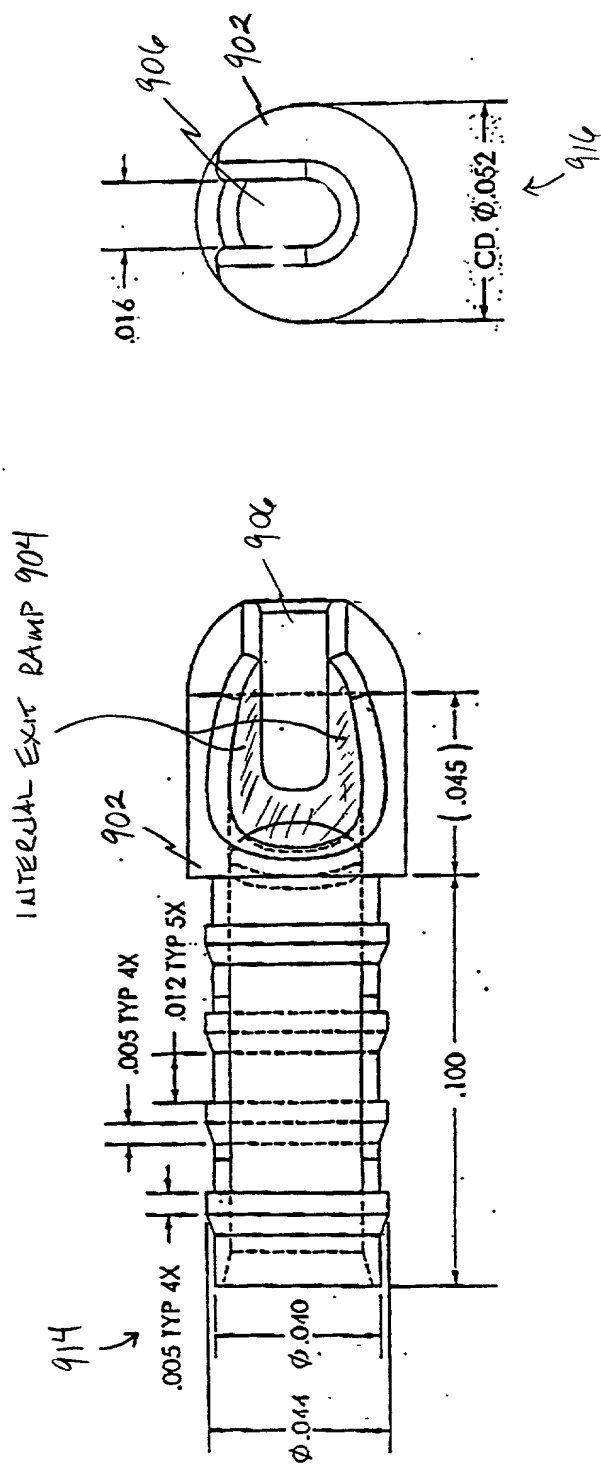
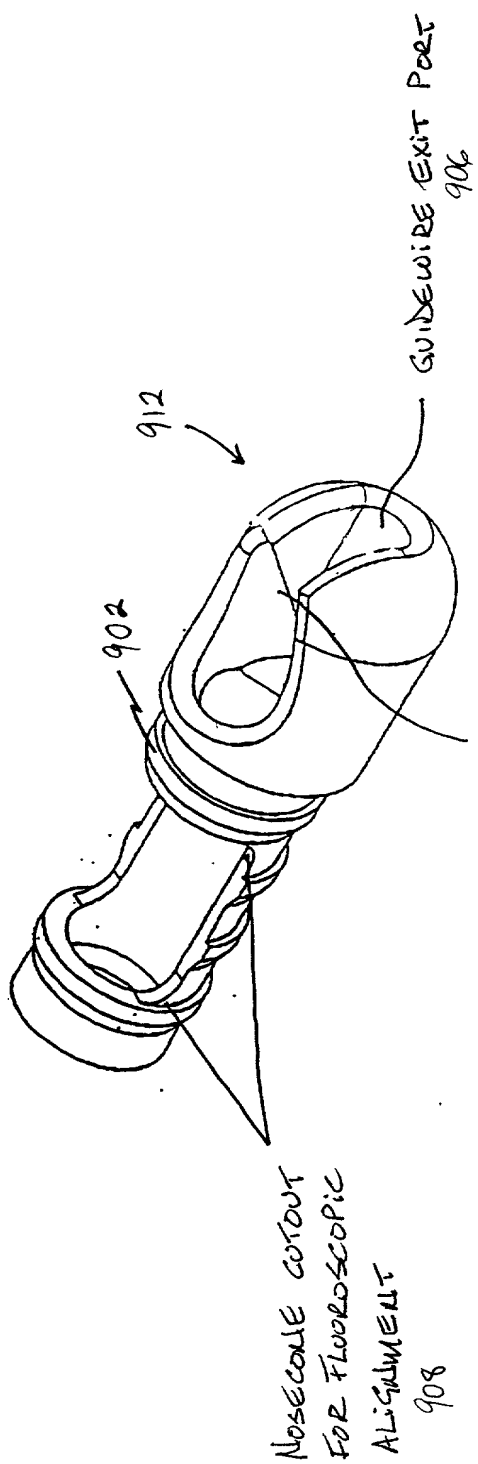


FIGURE 9A

950  
VESSEL WALL

VESSEL TRUE LUMEN 960

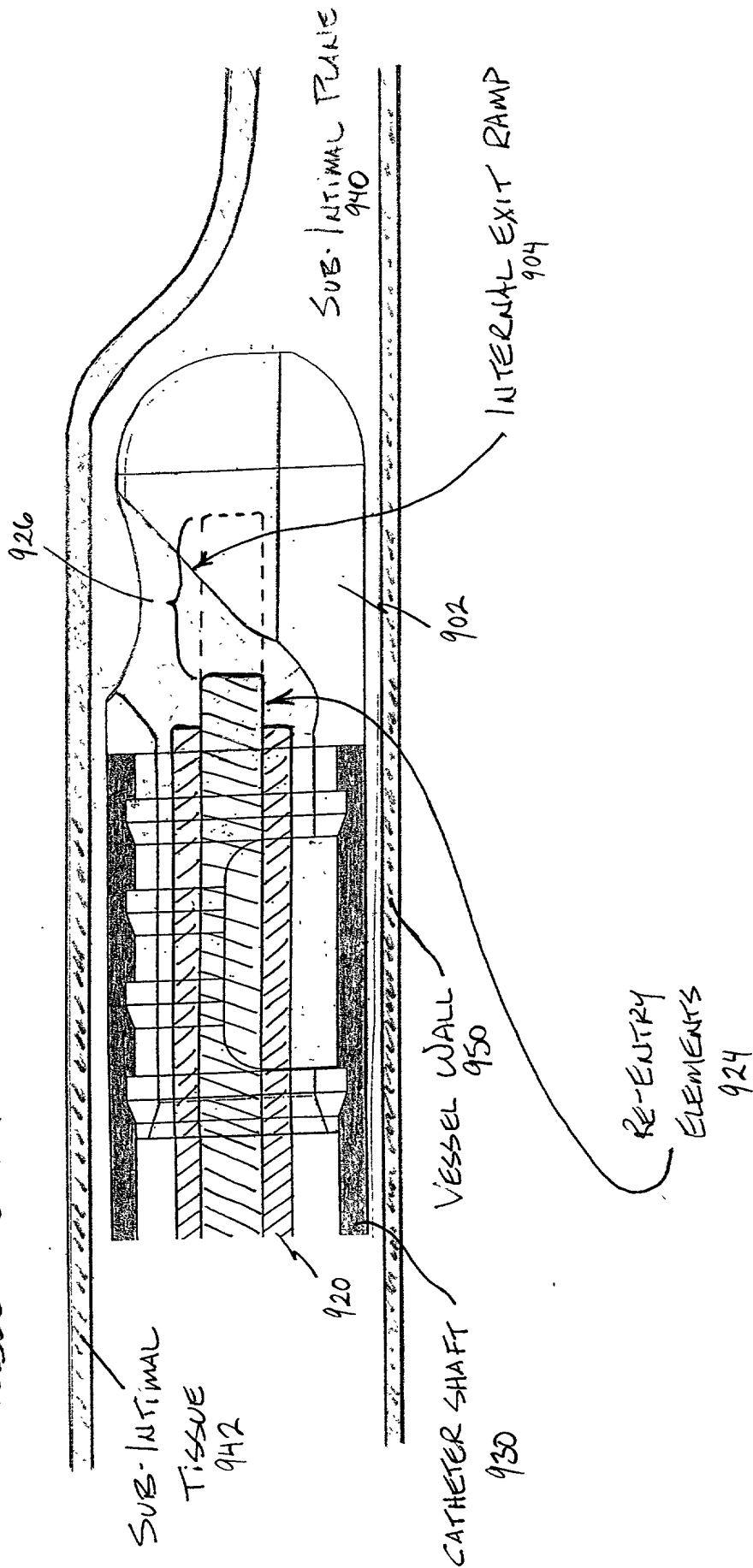


FIGURE 9B

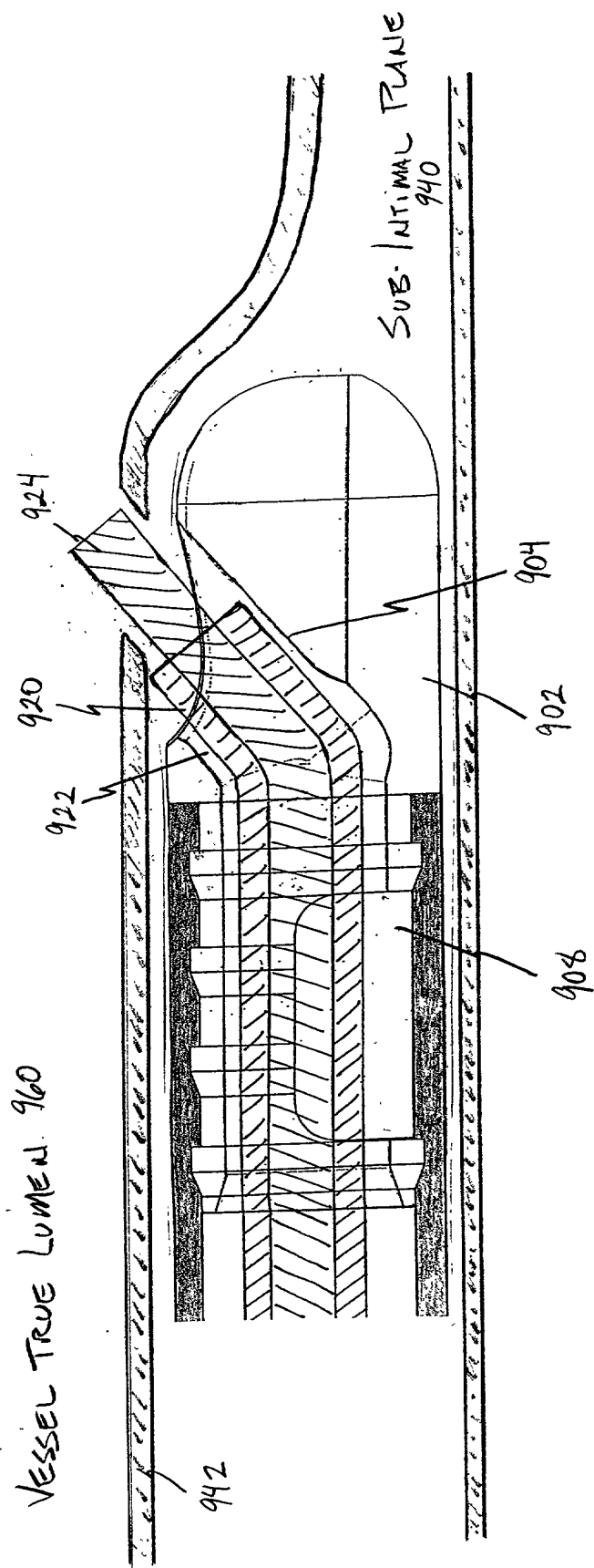


Figure 9C

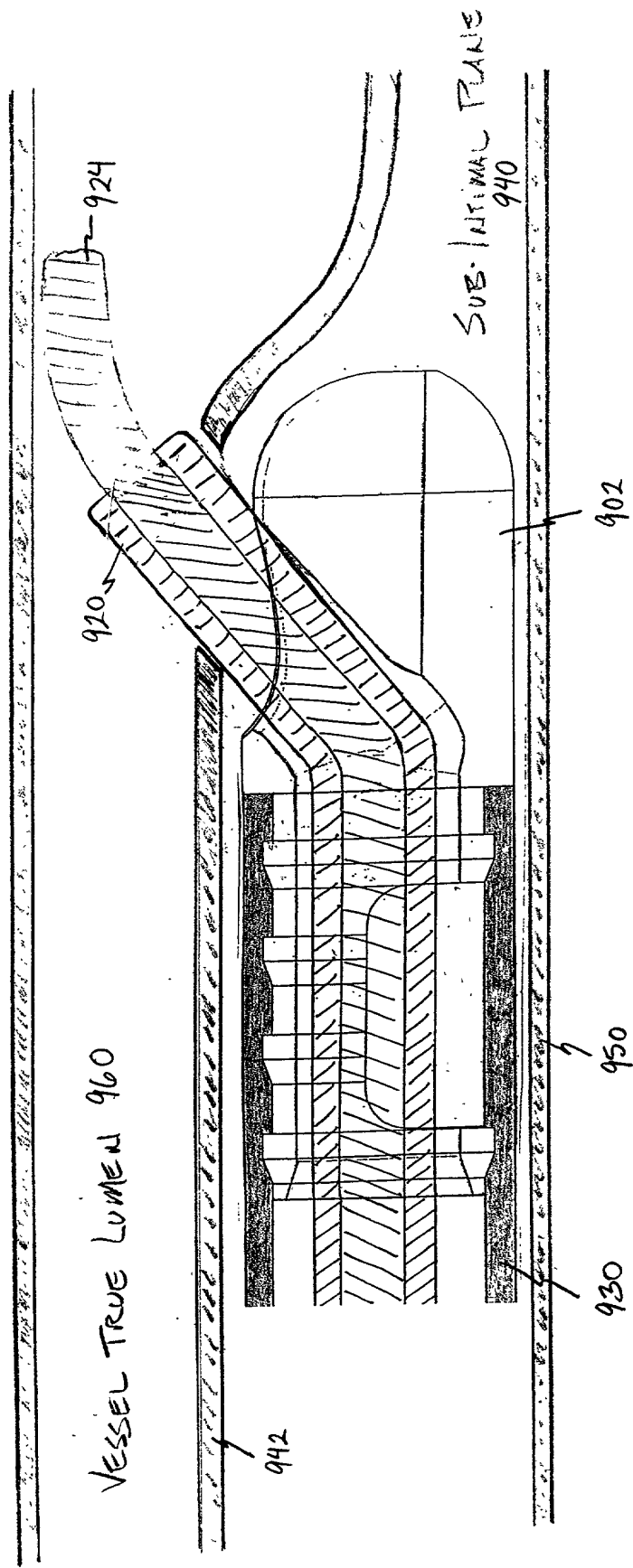


FIGURE 9D

VESSEL TRUE LUMEN 960

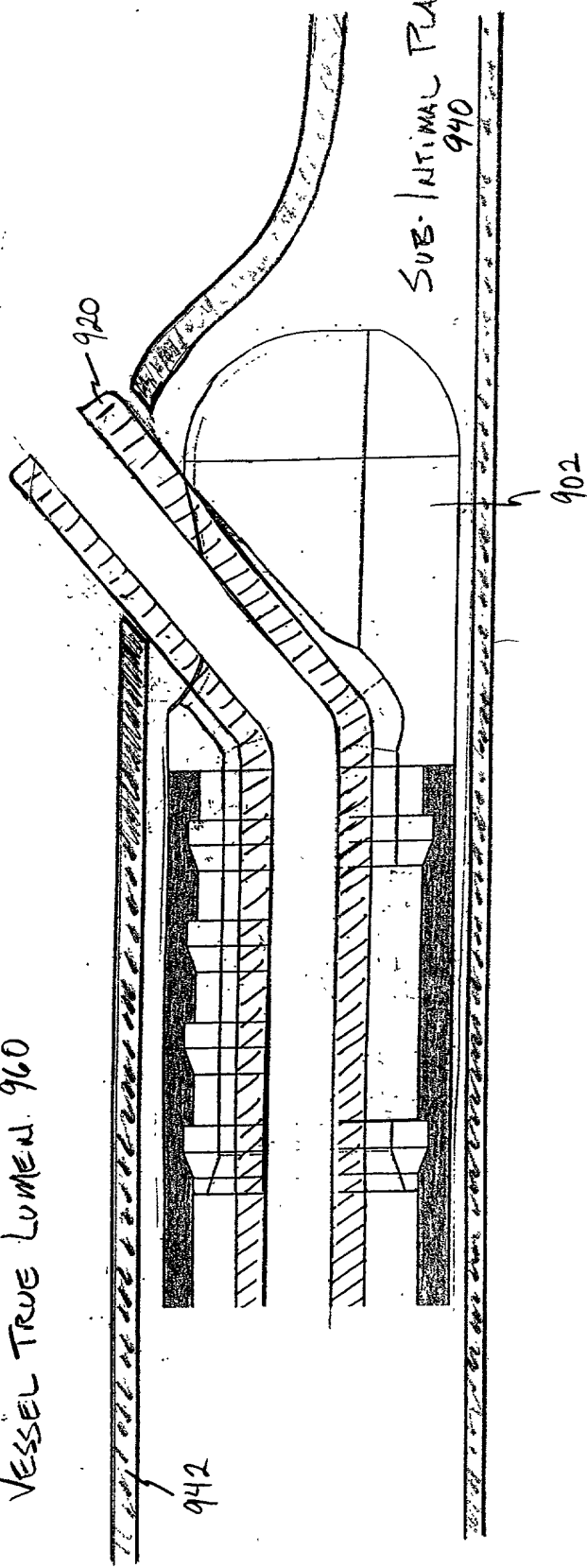


FIGURE 9E

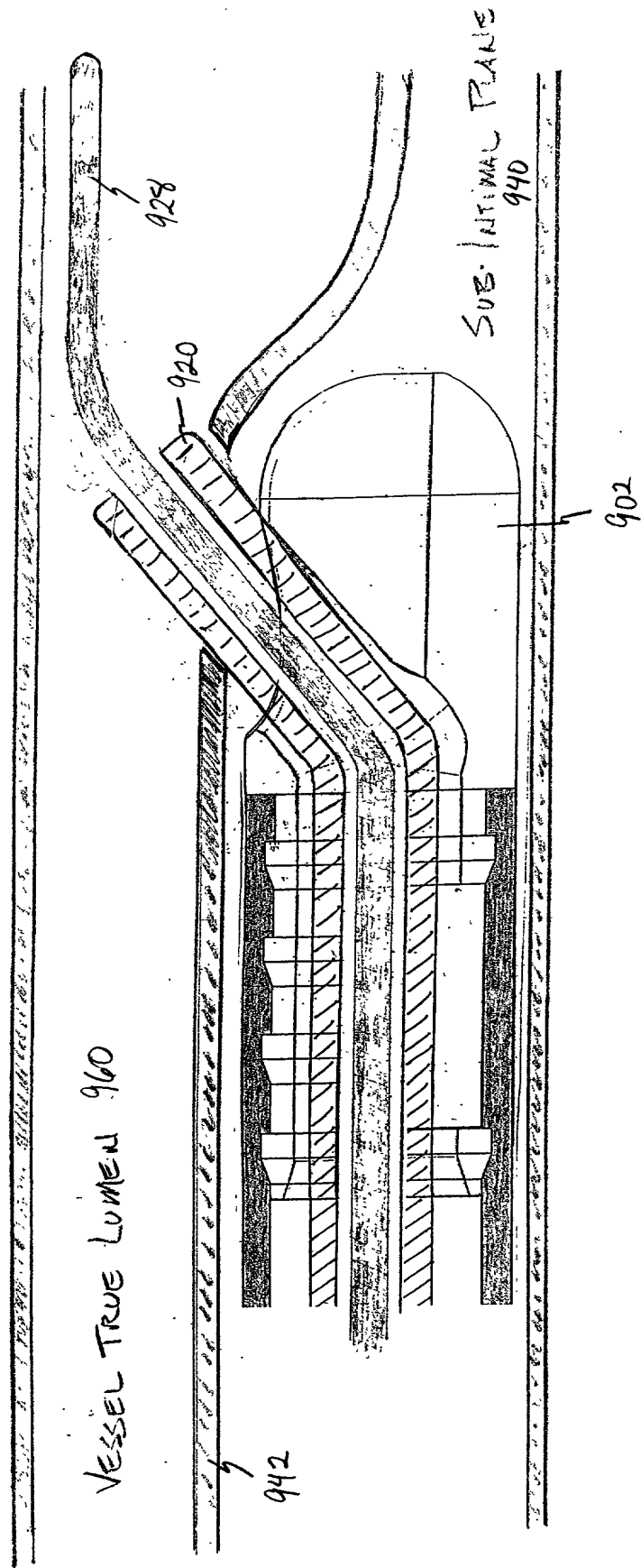


FIGURE 9F

FIG. 10A

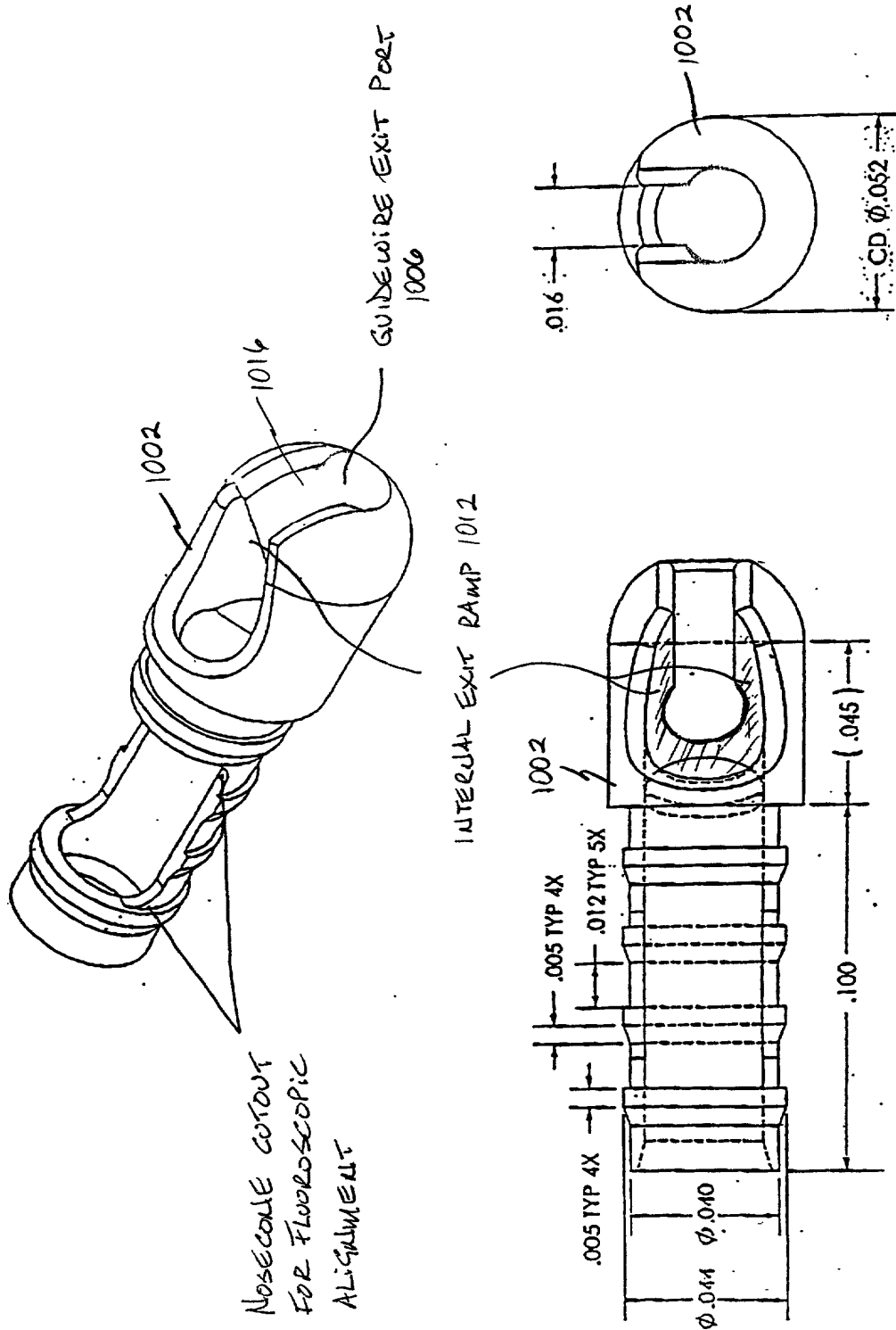


FIGURE 10A



FIG. 10A is a perspective view of the catheter assembly 1000 in a retracted position. The catheter shaft 1014 is shown in a retracted position, and the specialized guide wire 1010 is shown in a retracted position. The nosecone 1002 is shown in a retracted position. The internal ramp 1012 is shown in a retracted position. The distal taper 1014 is shown in a retracted position. The vacuum lumen 1002 is shown in a retracted position.

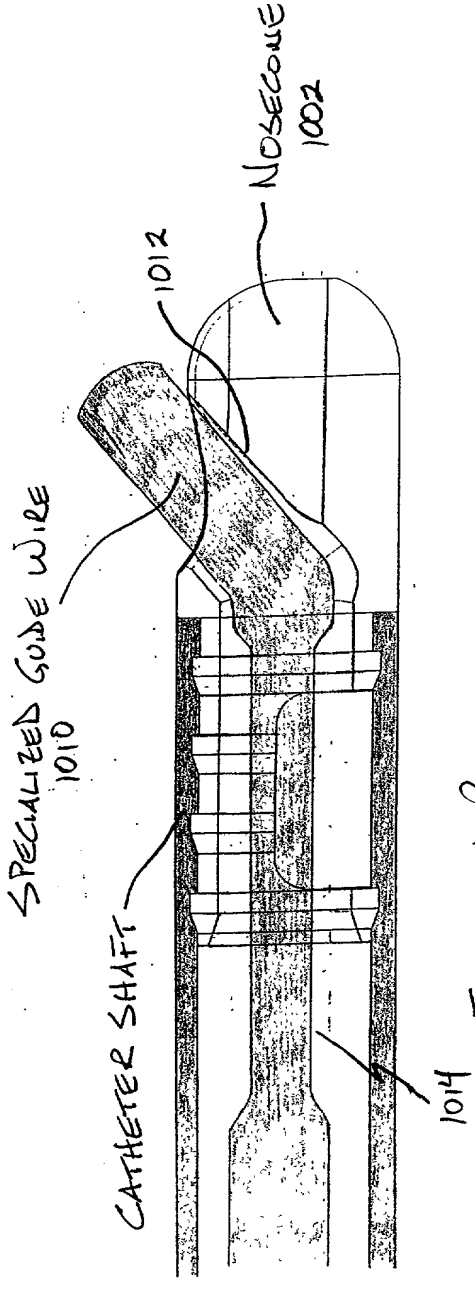


FIGURE 10B

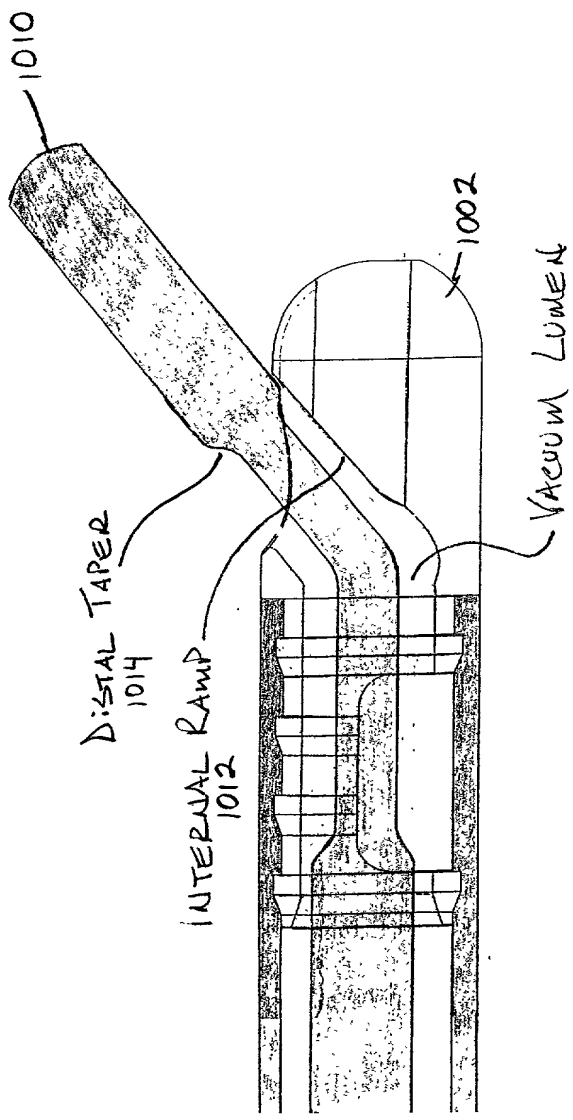


FIGURE 10C

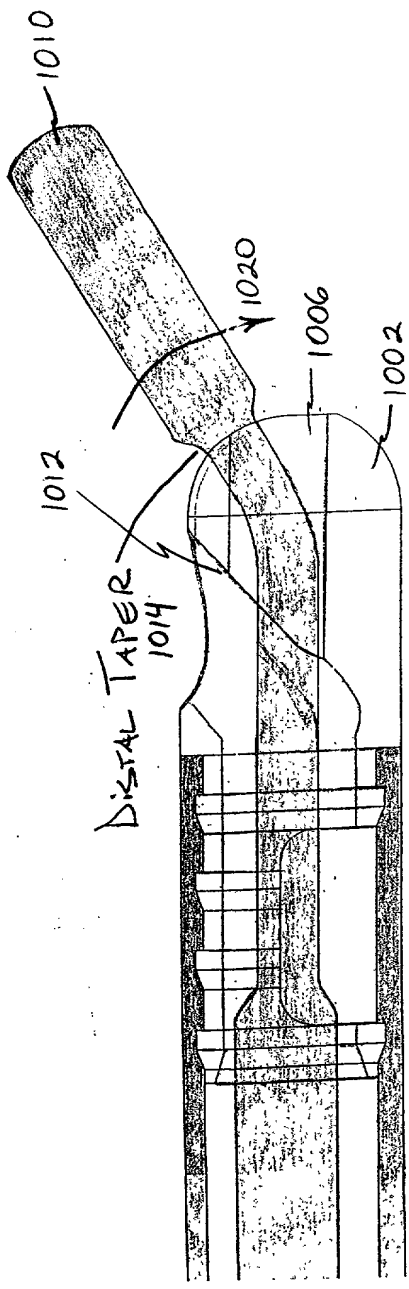


FIGURE 10D

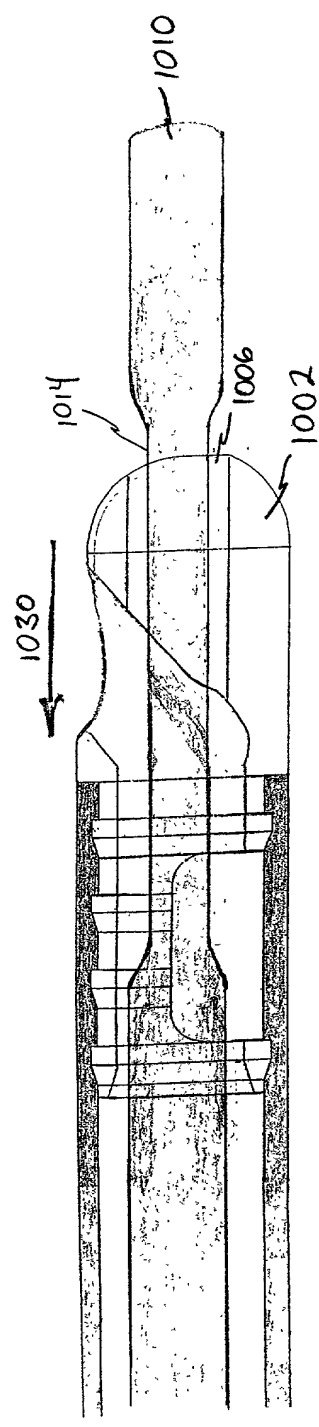


FIGURE 10E

1100  
↓

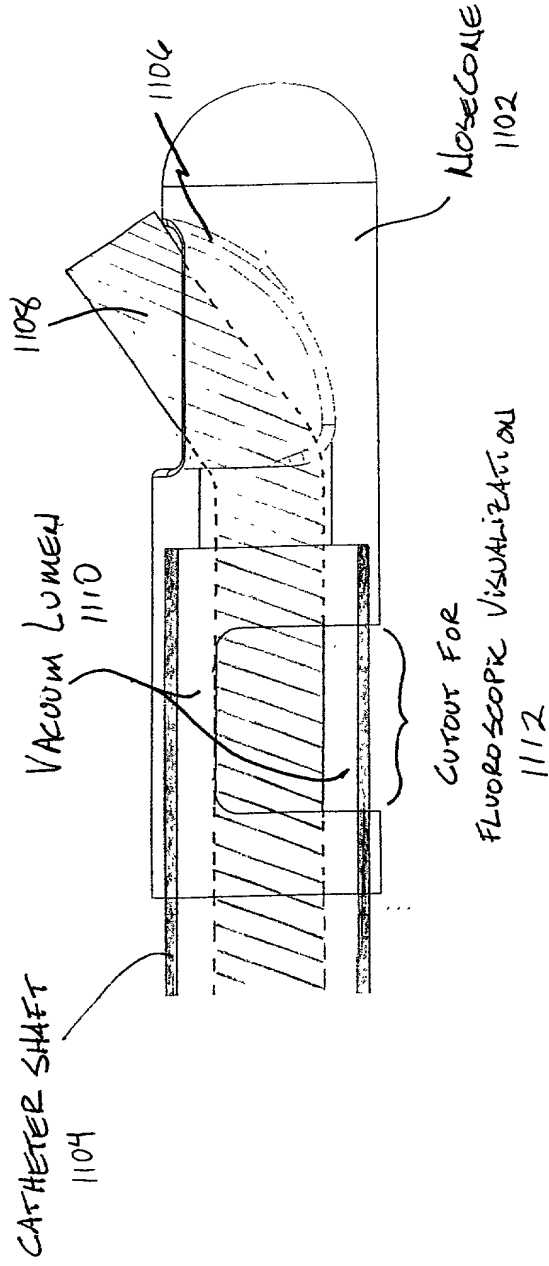


FIGURE 11

1200

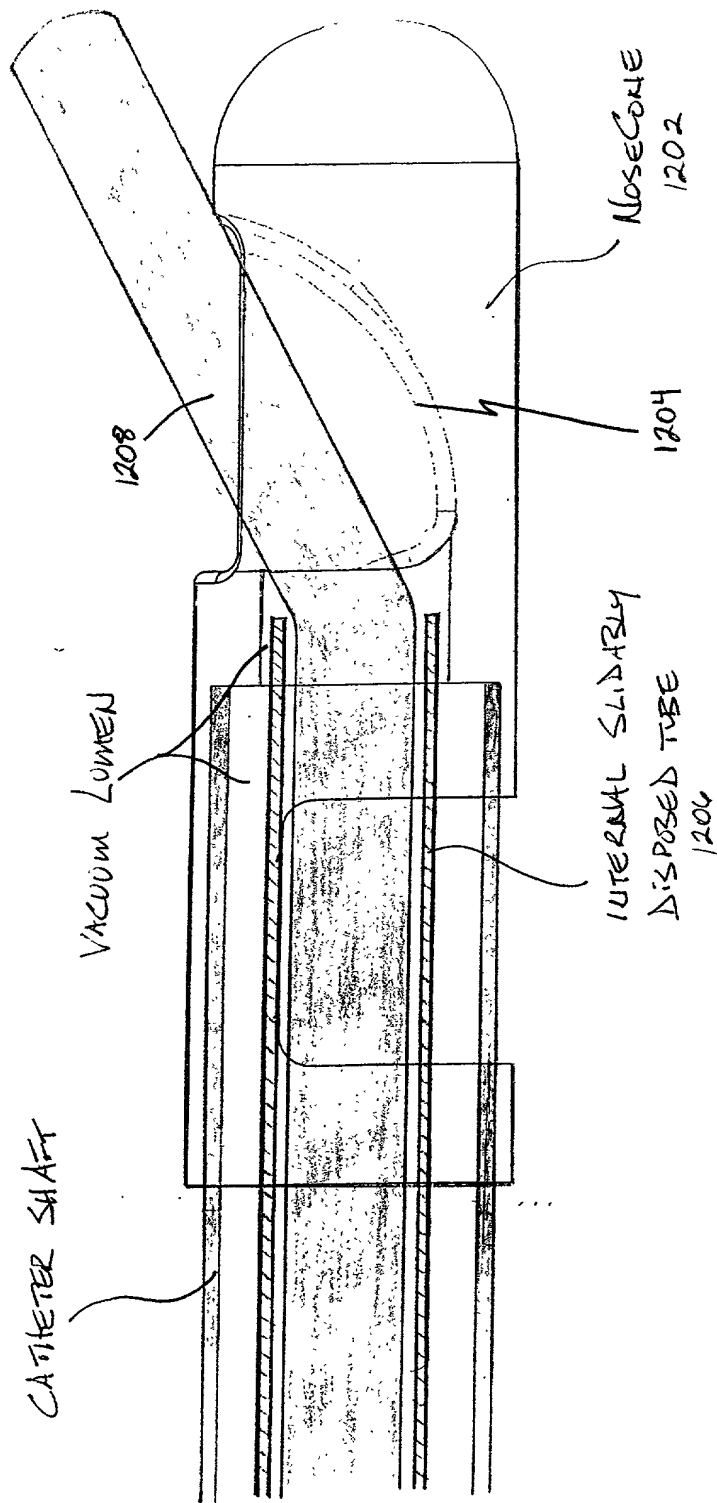


FIGURE 12A

FIG. 12B is a cross-sectional view of the catheter 1200 taken along line 12-12 of FIG. 12A, showing the internal components and the sliding tube 1206.

1200  
↓

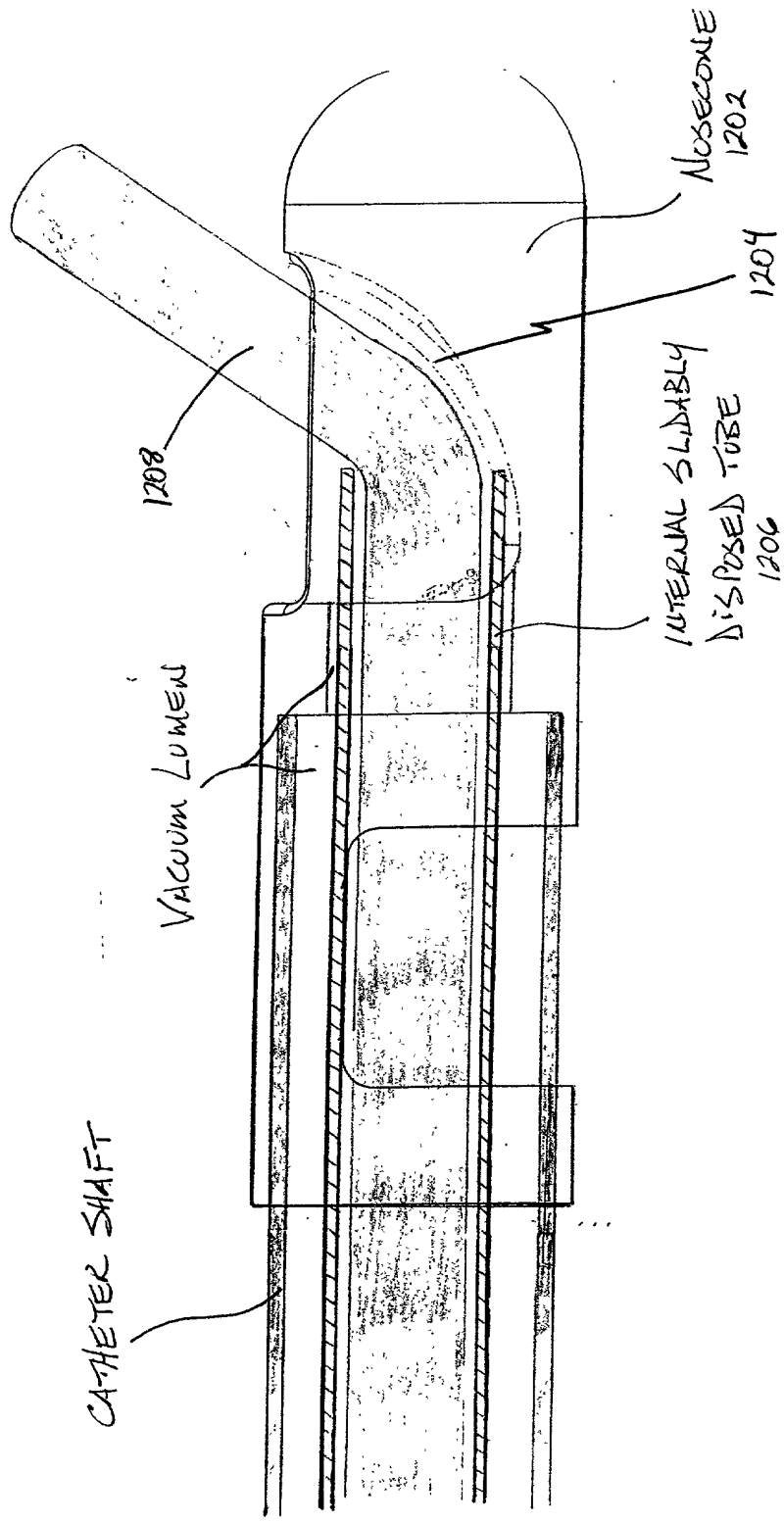


FIGURE 12B

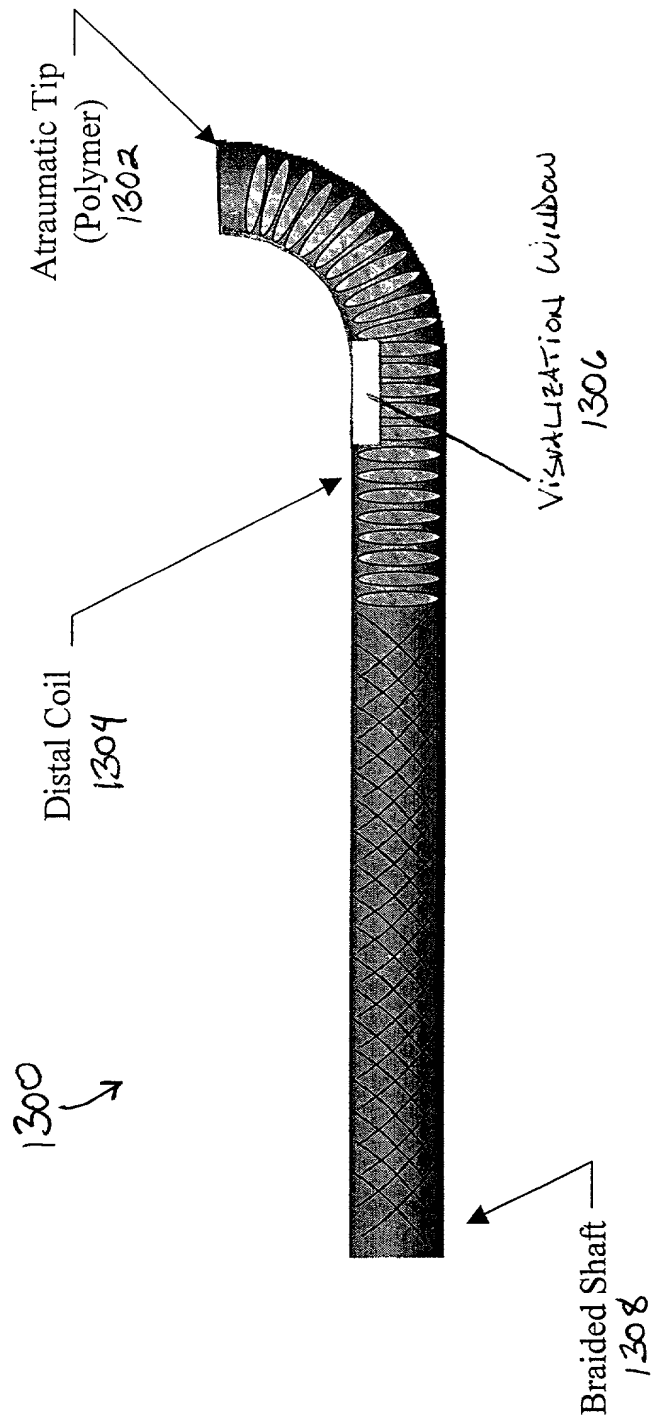


FIGURE 13

1400

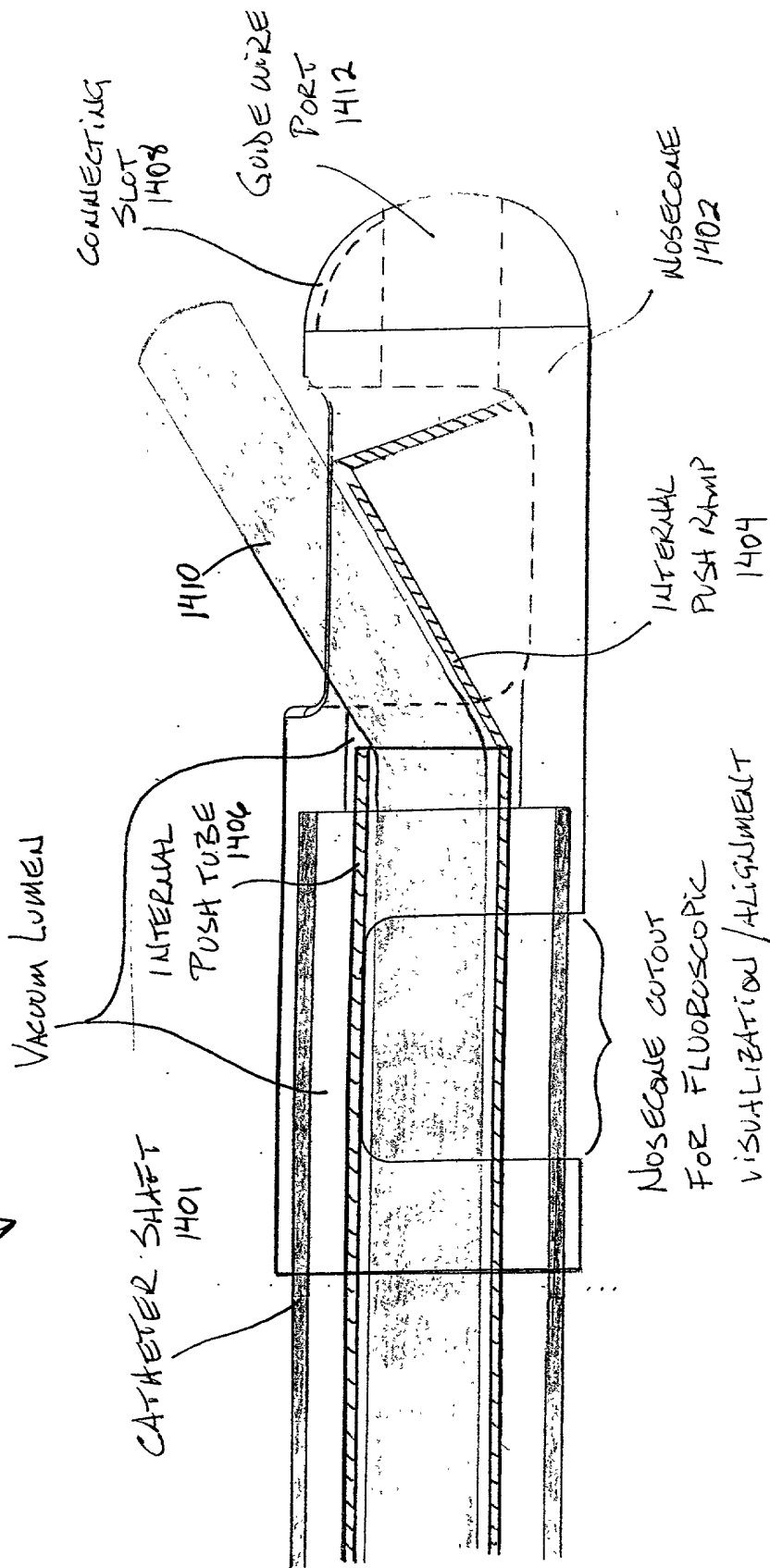


FIGURE 14A

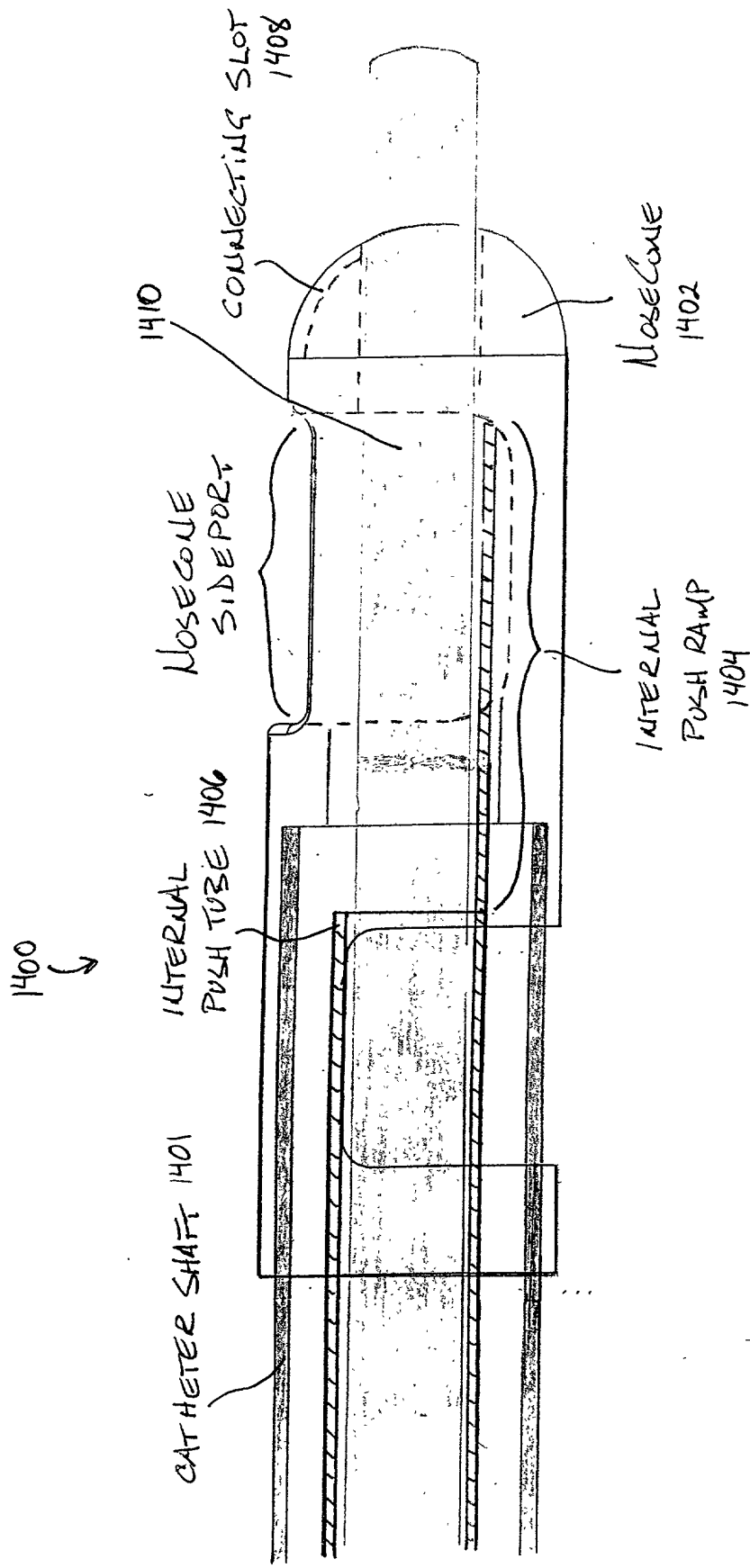


FIGURE 14B



1500

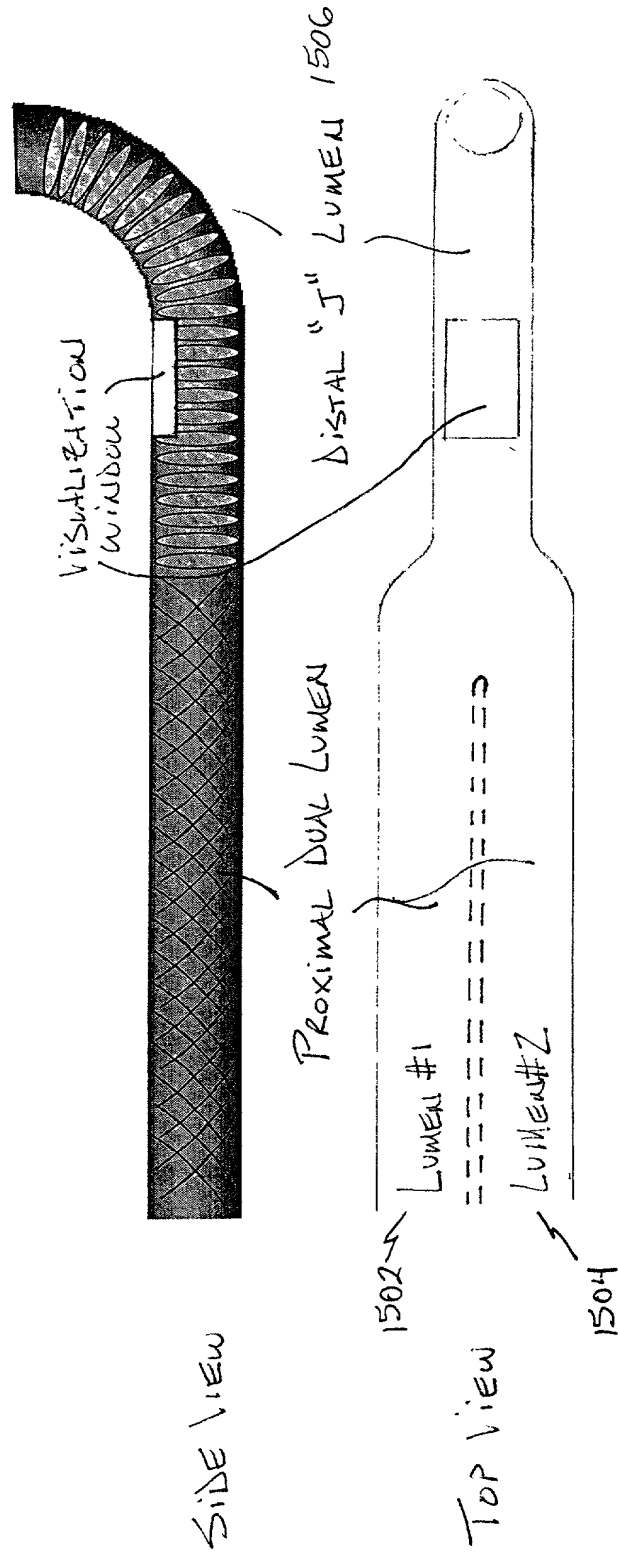


FIGURE 15

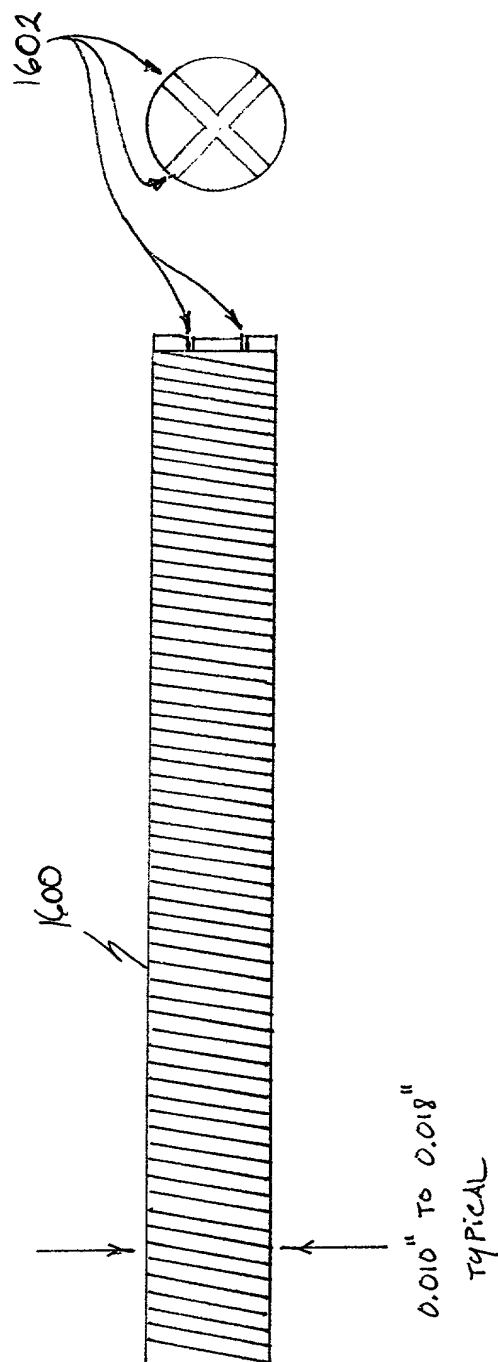


FIGURE 16

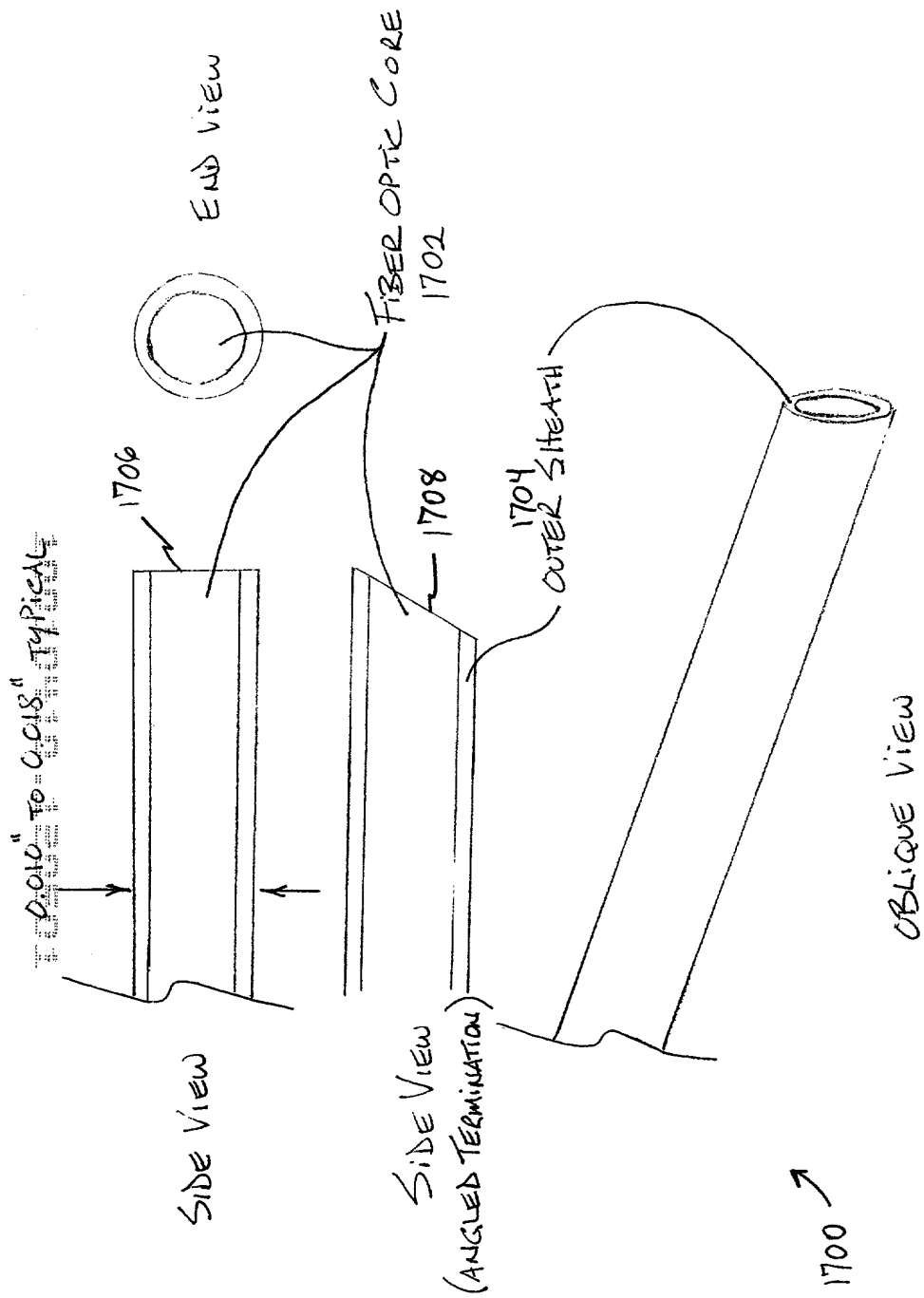


FIGURE 17A



FIG. 18 is a perspective view of the device of FIG. 17, showing the device in a side view. The device is a cylindrical structure with a central core and a surrounding sheath. The sheath is made of a polymer material and has a thickness of 0.015-0.020 inches. The device is shown in a side view, with the central core and the surrounding sheath clearly visible. The sheath is labeled 1800 and the central core is labeled 1802. The device is shown in a perspective view, with the top and bottom surfaces clearly visible. The top surface is labeled 1804 and the bottom surface is labeled 1806. The device is shown in a perspective view, with the top and bottom surfaces clearly visible. The top surface is labeled 1804 and the bottom surface is labeled 1806.

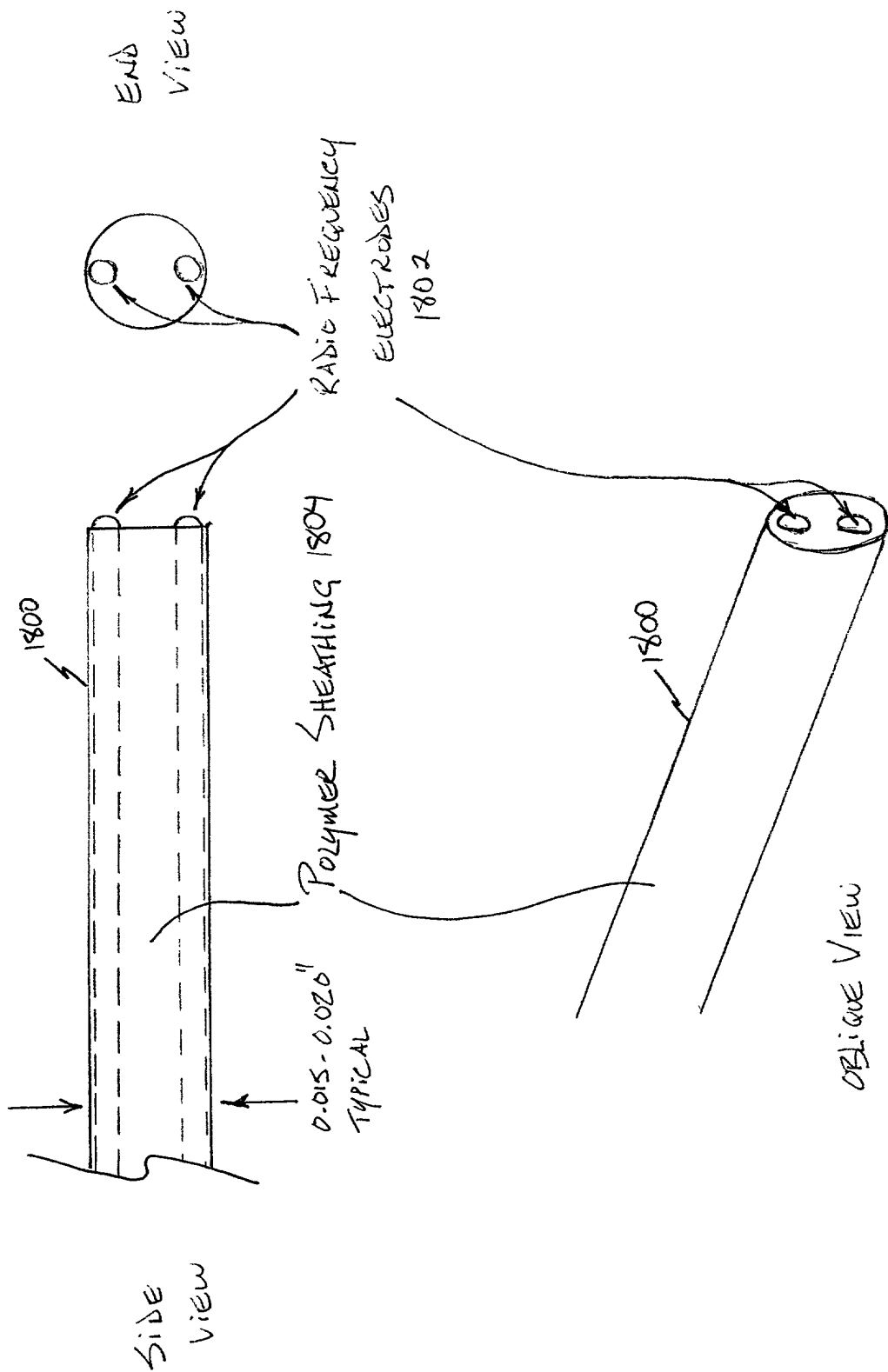


FIGURE 18

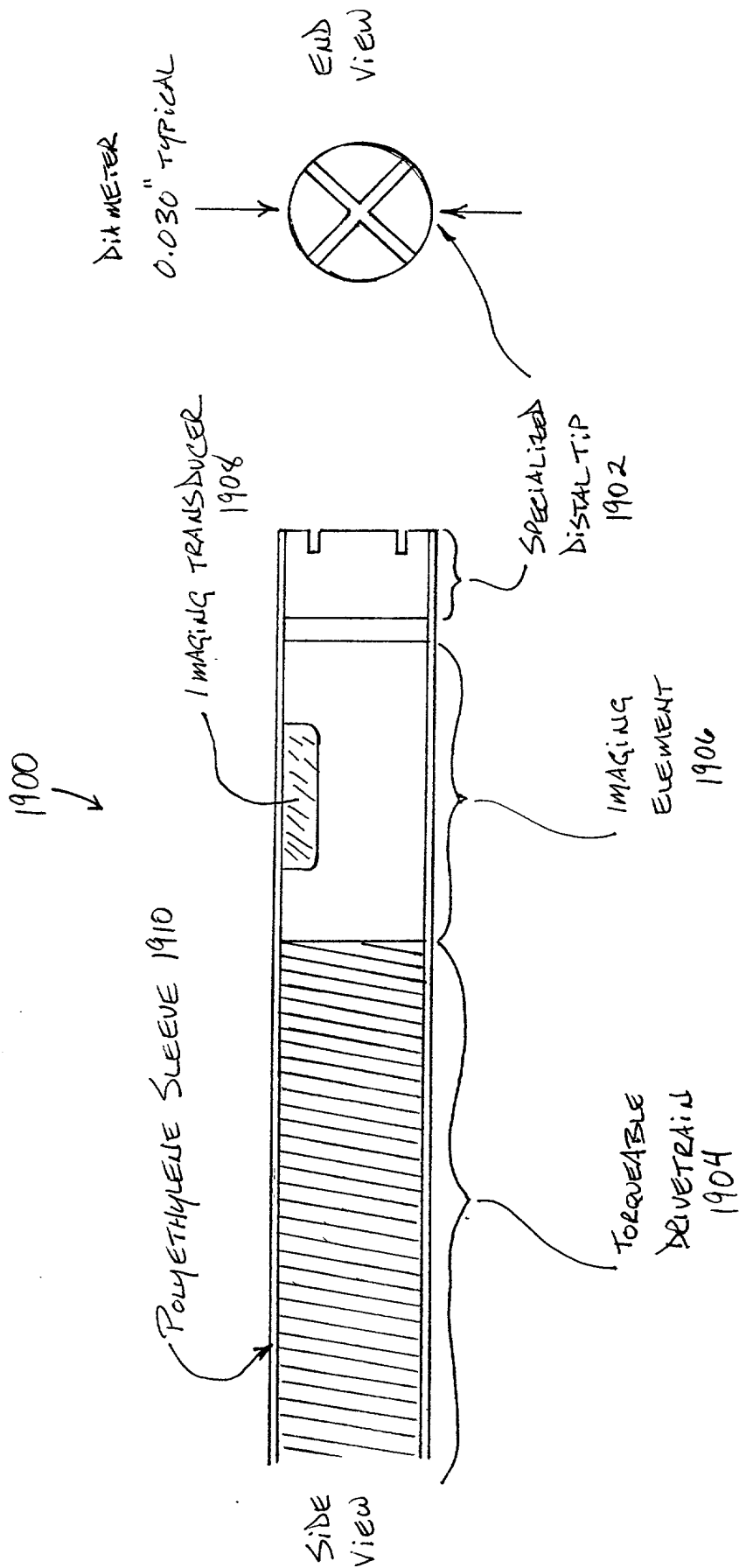


FIGURE 19

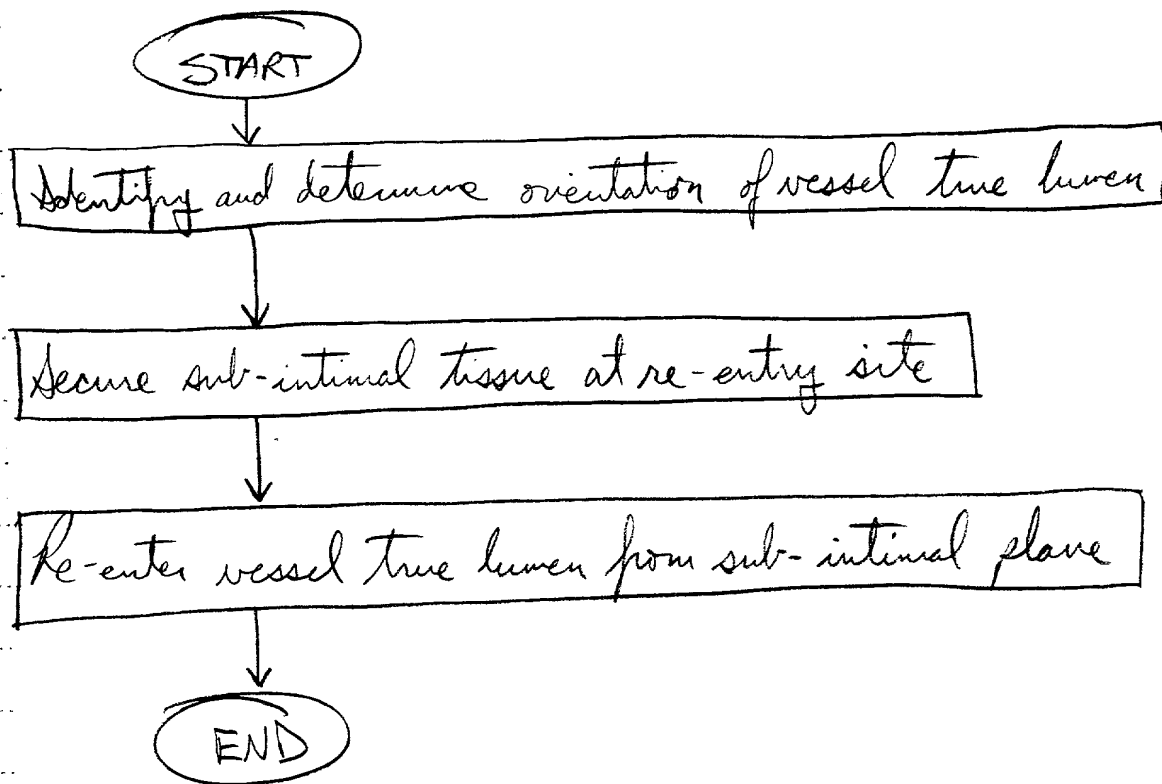


FIGURE 20

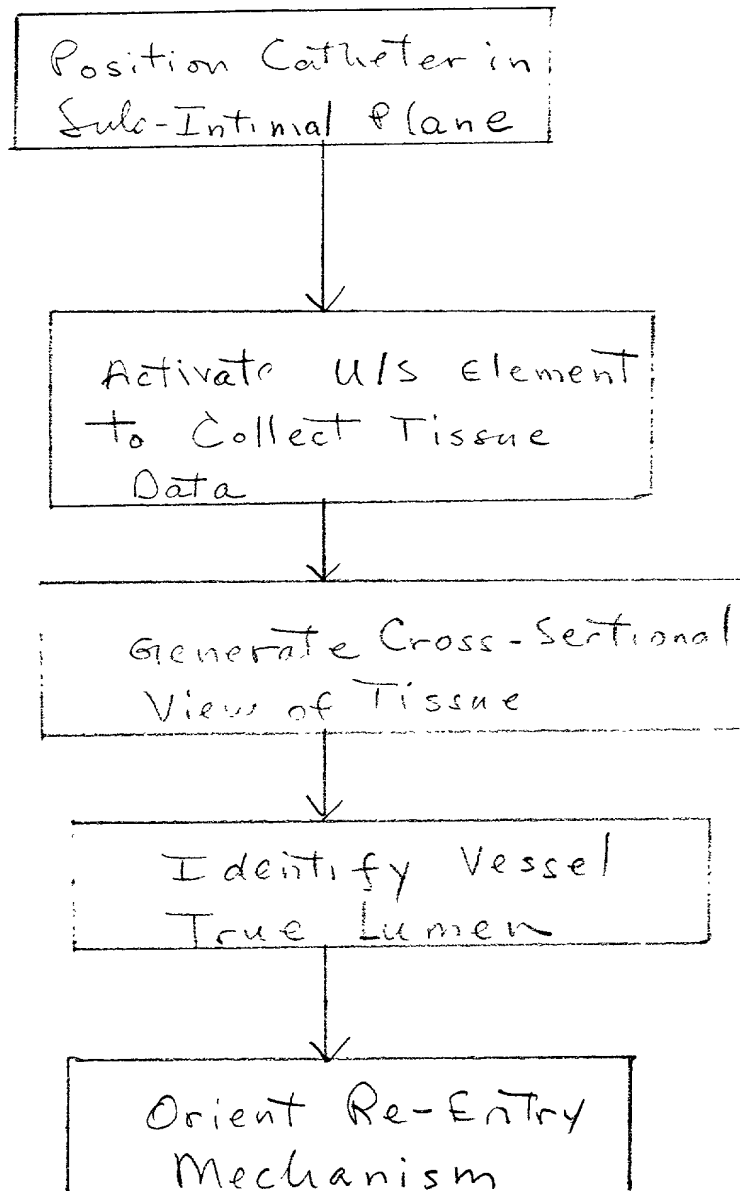


Figure 21



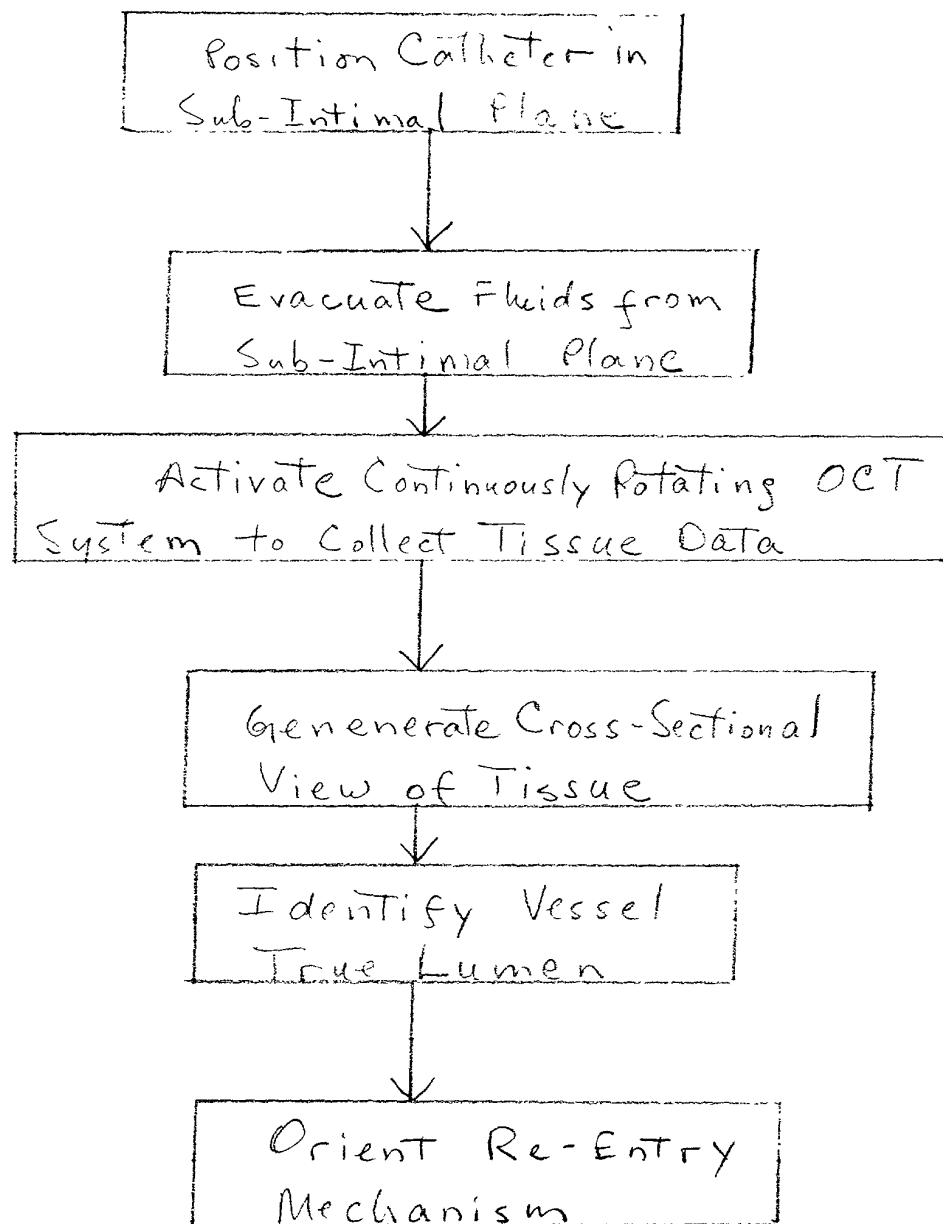


Figure 22

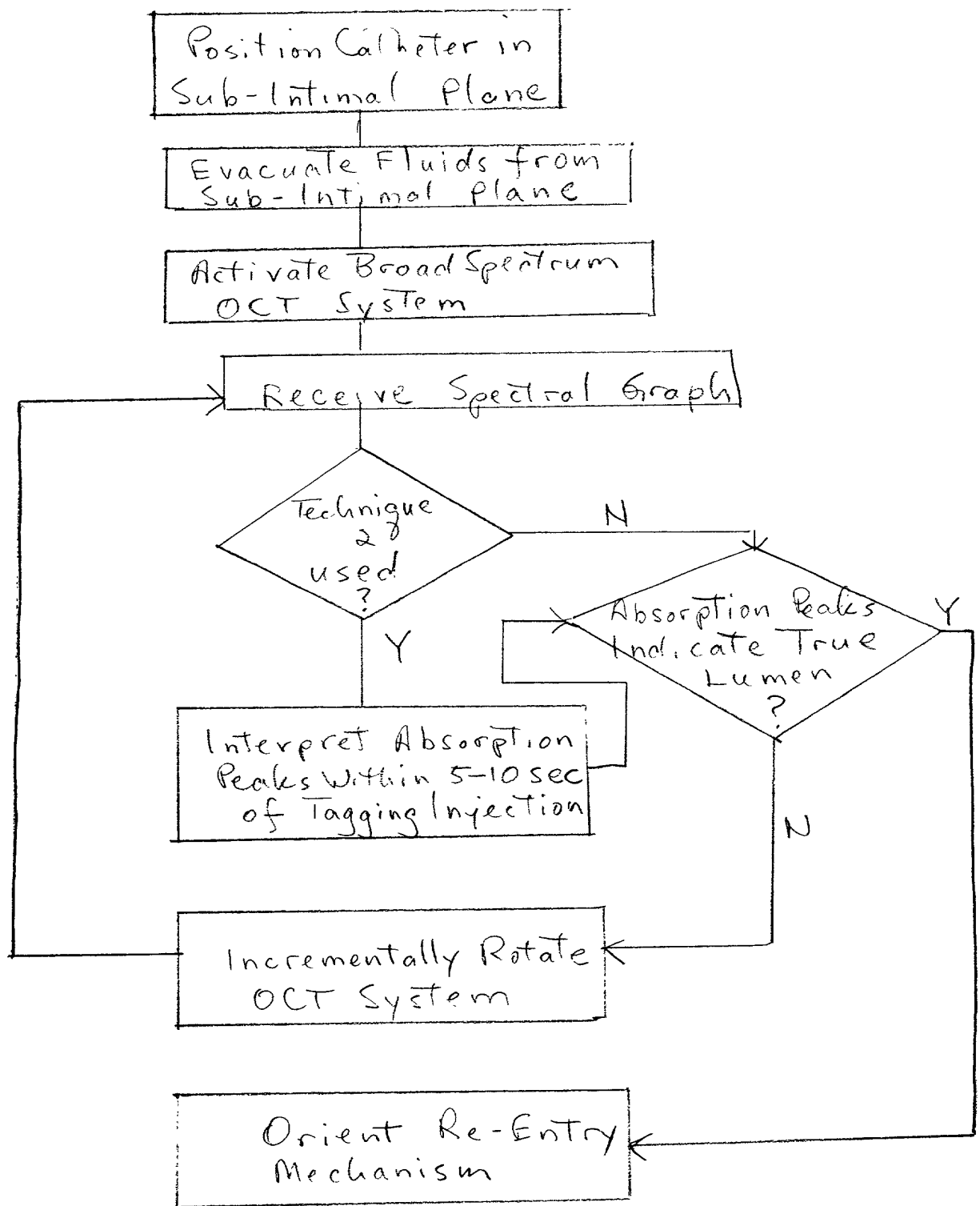


FIGURE 23

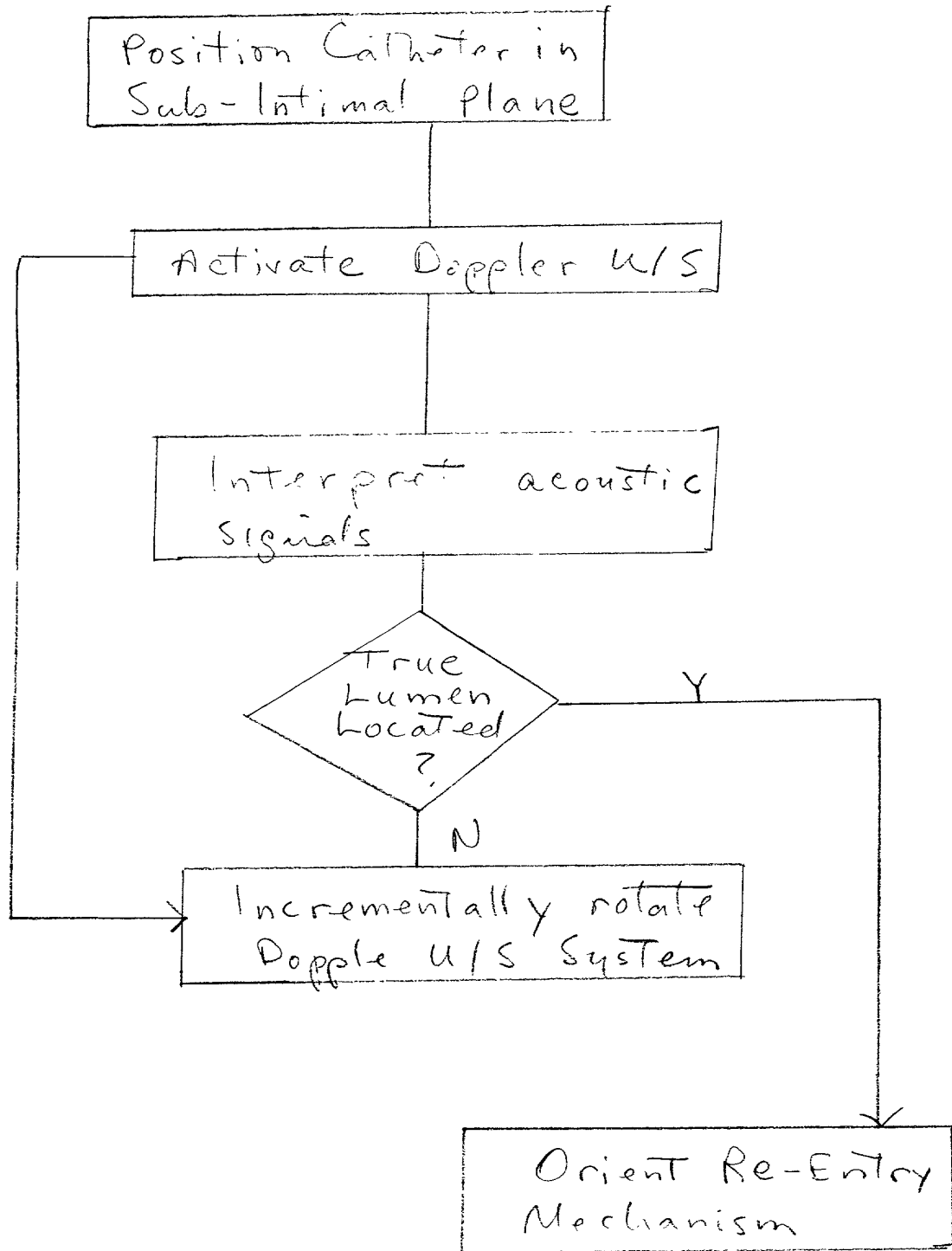


Figure 24

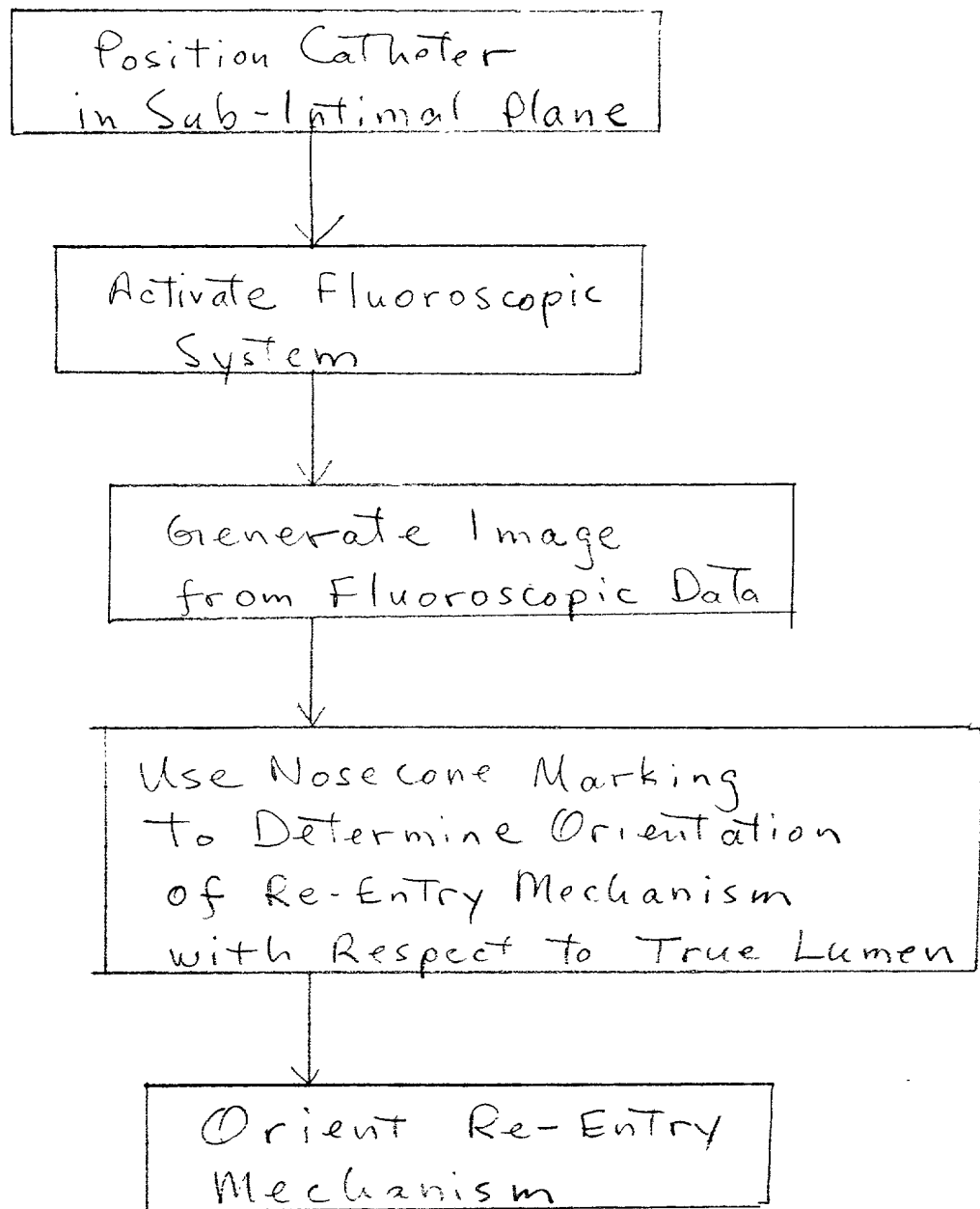


Figure 25

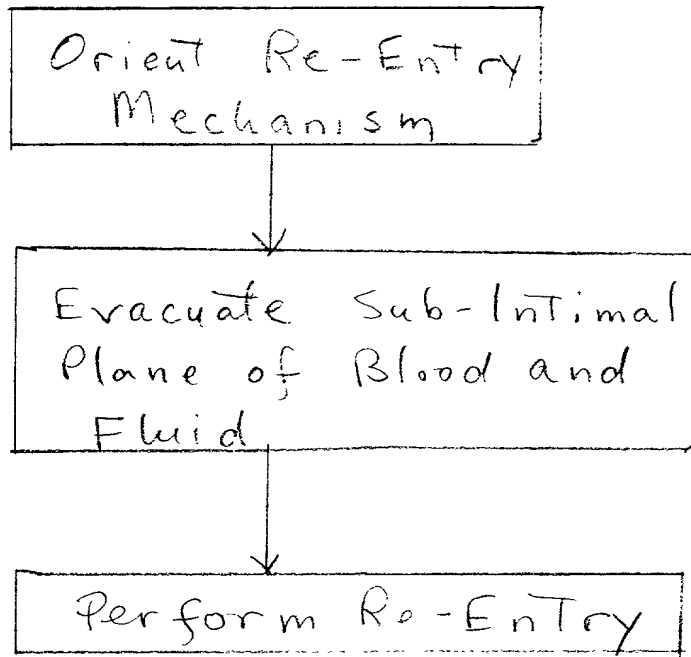


Figure 26

Orient Re-Entry  
Mechanism



Evacuate Sub-Intimal  
Plane of Blood and  
Fluid



Apply Further Vacuum  
to Invaginate Tissue  
into Catheter



Perform Re-Entry

Figure 27

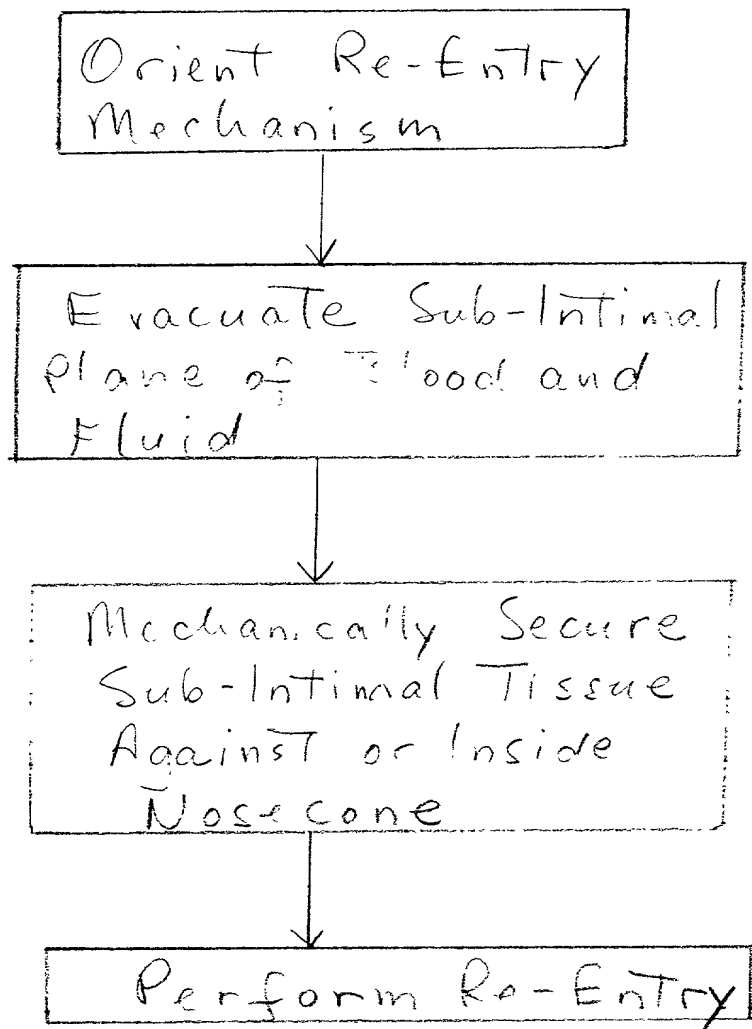


Figure 28

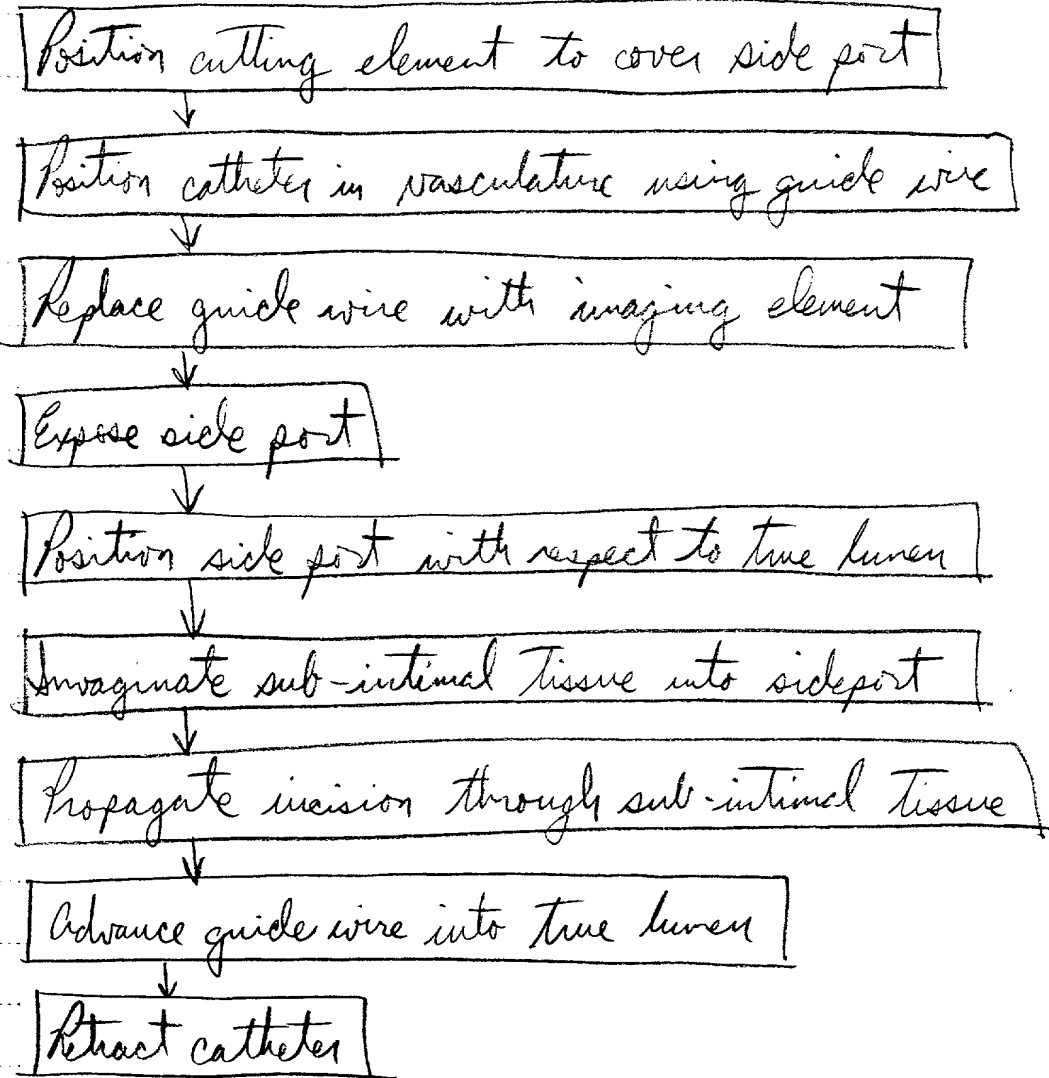


FIGURE 29



Position guide wire in sub-intimal space

Retract cannula

Position catheter in vasculature

Position side port with respect to true lumen

Position guide wire proximal to nosecone distal end

Lock sub-intimal tissue onto nosecone surface using vacuum

Advance cannula distally and guide out of side port via nosecone internal ramps

Pierce sub-intimal tissue

Advance guide wire into true lumen

Retract cannula

FIGURE 30

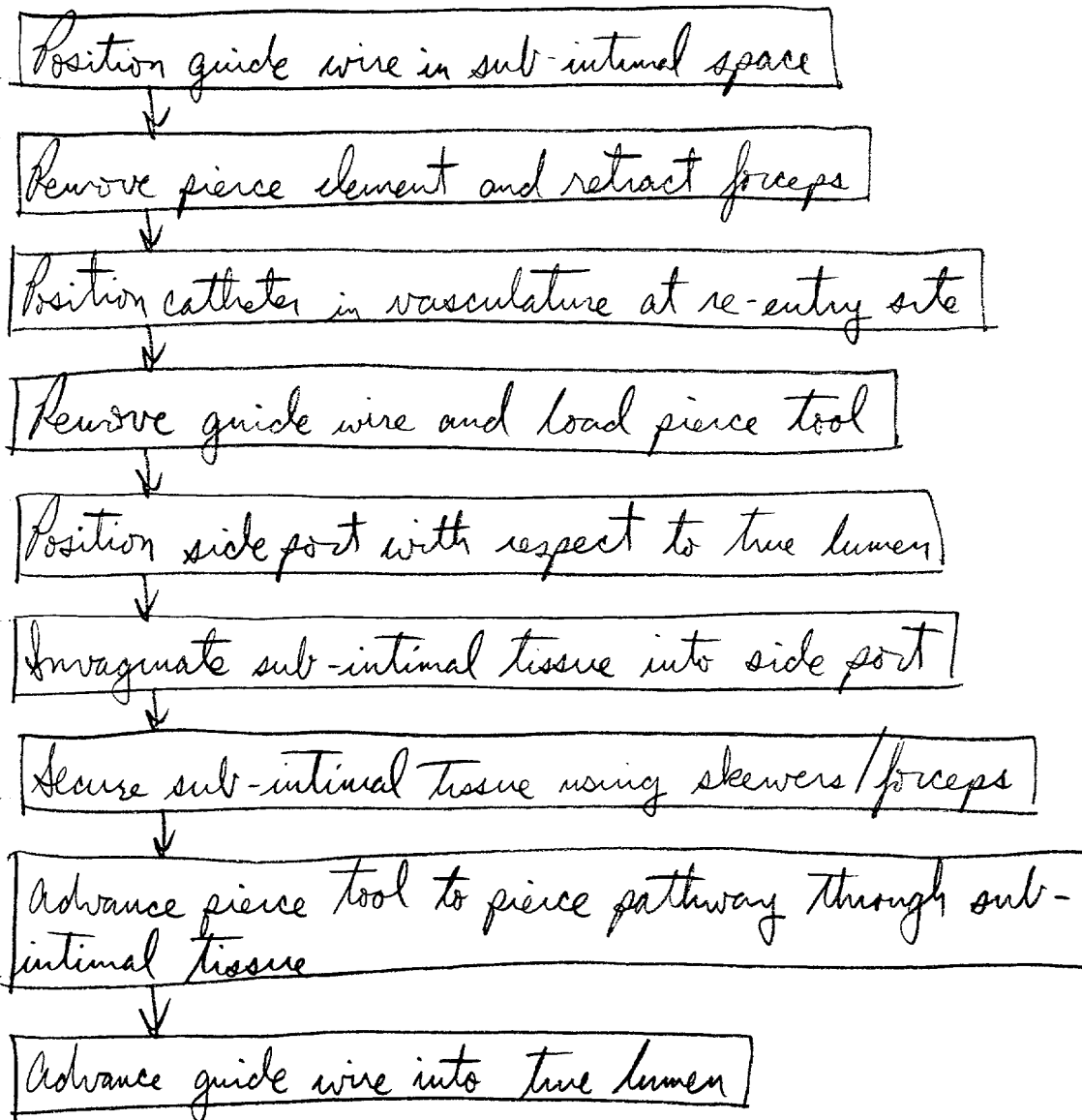


FIGURE 31

Position catheter in vasculature using guide wire



Remove guide wire and advance visualization element



Align side port with respect to vessel true lumen



Lock sub-intimal tissue on surface of catheter using applied vacuum



Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

FIGURE 32

Position catheter in vasculature using guide wire



Remove guide wire and replace with specialized guide wire



Activate visualization element



Align side port with respect to vessel true lumen



Invaginate sub-intimal tissue into nosecone



Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

FIGURE 33

Retract cannula

↓  
Position catheter in vasculature using guide wire

↓  
Align side port with respect to true lumen

↓  
Position guide wire proximal to nosecone distal end

↓  
Lock sub-intimal tissue onto nosecone using vacuum

↓  
Advance cannula distally along internal ramp until  
in secure purchase with sub-intimal tissue

↓  
Advance guide wire until tip coincident with  
cannula distal tip

↓  
Push and/or rotate guide wire distal tip through sub-  
intimal tissue into vessel true lumen

FIGURE 34

Position catheter in vasculature with respect to vessel true lumen



Advance specialized guide wire proximally relative to distal end of nose cone



Lock sub-intimal tissue onto nosecone using vacuum



Rotate/advance specialized guide wire to engage internal rails of nosecone



Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen



Advance specialized guide wire further distally until tapered section translates through nosecone slot into nosecone distal end port



Retract catheter

FIGURE 35

Position catheter in vasculature with respect to vessel true lumen

↓  
Retract guide wire and advance visualization element

↓  
Rotate side port to face re-entry site

↓  
Remove visualization element and advance guide wire

↓  
Lock sub-intimal tissue onto nosecone using vacuum

↓  
Advance guide wire into nosecone until in contact with sub-intimal tissue

↓  
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

↓  
Retract catheter

FIGURE 36

Position guide wire appropriately in vasculature

Retract push tube

Advance catheter to vascular region of occlusion over the guide wire

Control guide wire deployment angle from nose cone with position of push tube

Advance push tube distally to position guide wire at re-entry site

Push guide wire through sub-intimal tissue into vessel true lumen

FIGURE 37



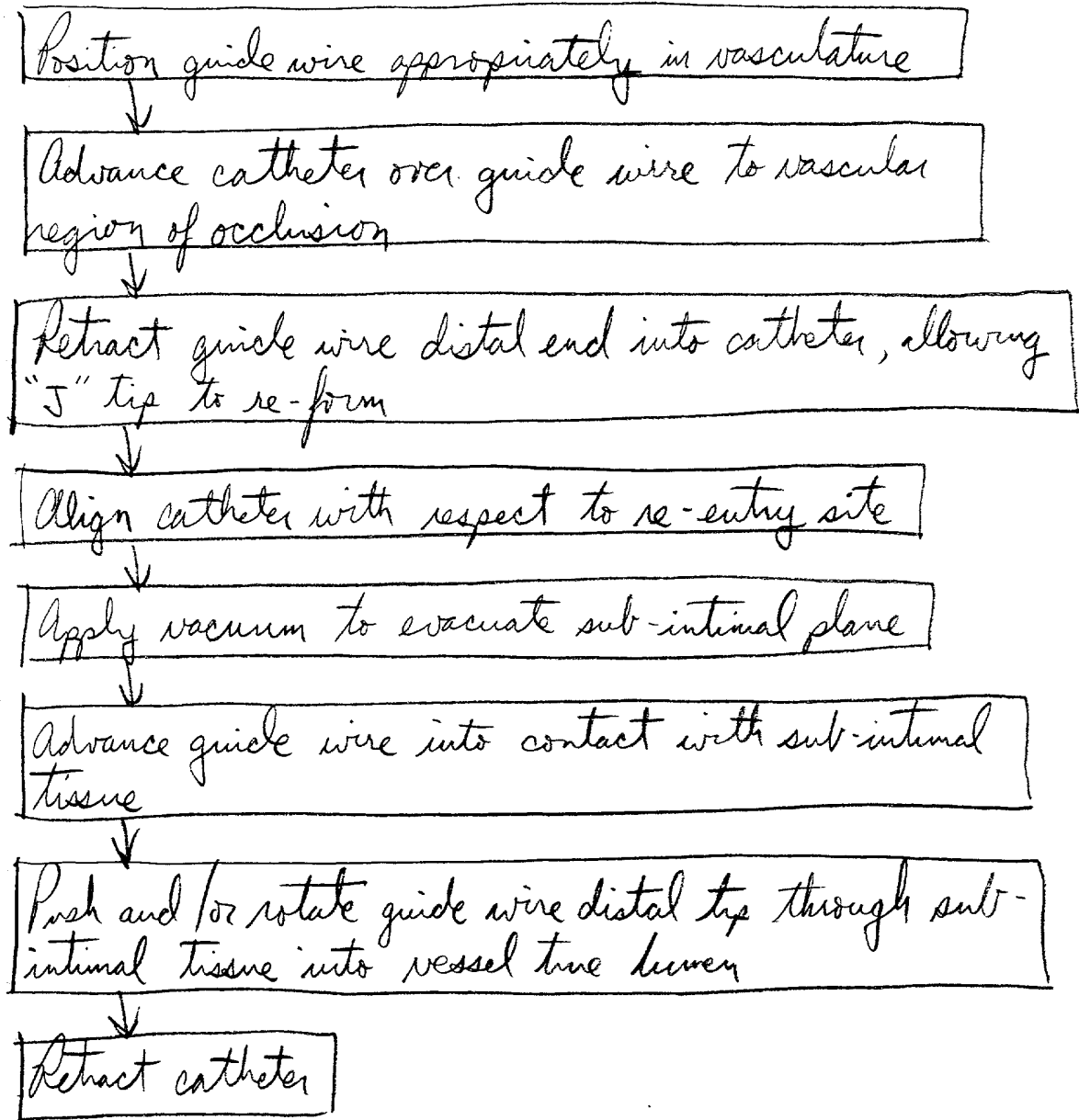


FIGURE 38

Retract push tube



Advance catheter over guide wire to vascular region of occlusion



Retract guide wire to a position proximal to the internal ramp



Align catheter with respect to re-entry site



Evacuate sub-intimal plane using vacuum



Advance push tube to deploy internal push ramps



Advance guide wire into contact with sub-intimal tissue via deployed push ramps



Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen



Retract catheter

FIGURE 39

Load a first lumen with working element

Advance catheter over guide wire to vascular region of occlusion using a second lumen

Retract guide wire distal end into catheter, allowing "J" tip to re-form

Align catheter with respect to re-entry site

Evacuate sub-intimal plane

Establish path into vessel true lumen using working element

Retract working element

Advance guide wire into vessel true lumen

Retract catheter

FIGURE 40

Load a first lumen with visualization element

Advance catheter over guide wire to vascular region of occlusion using a second lumen

Remove guide wire and replace with re-entry wire

Advance visualization element into distal single lumen

Align catheter with respect to re-entry site

Retract visualization element to dual lumen region

Evacuate sub-intimal plane

Establish path into vessel true lumen using re-entry wire

Remove re-entry wire and replace with guide wire into vessel true lumen

Retract catheter

FIGURE 41

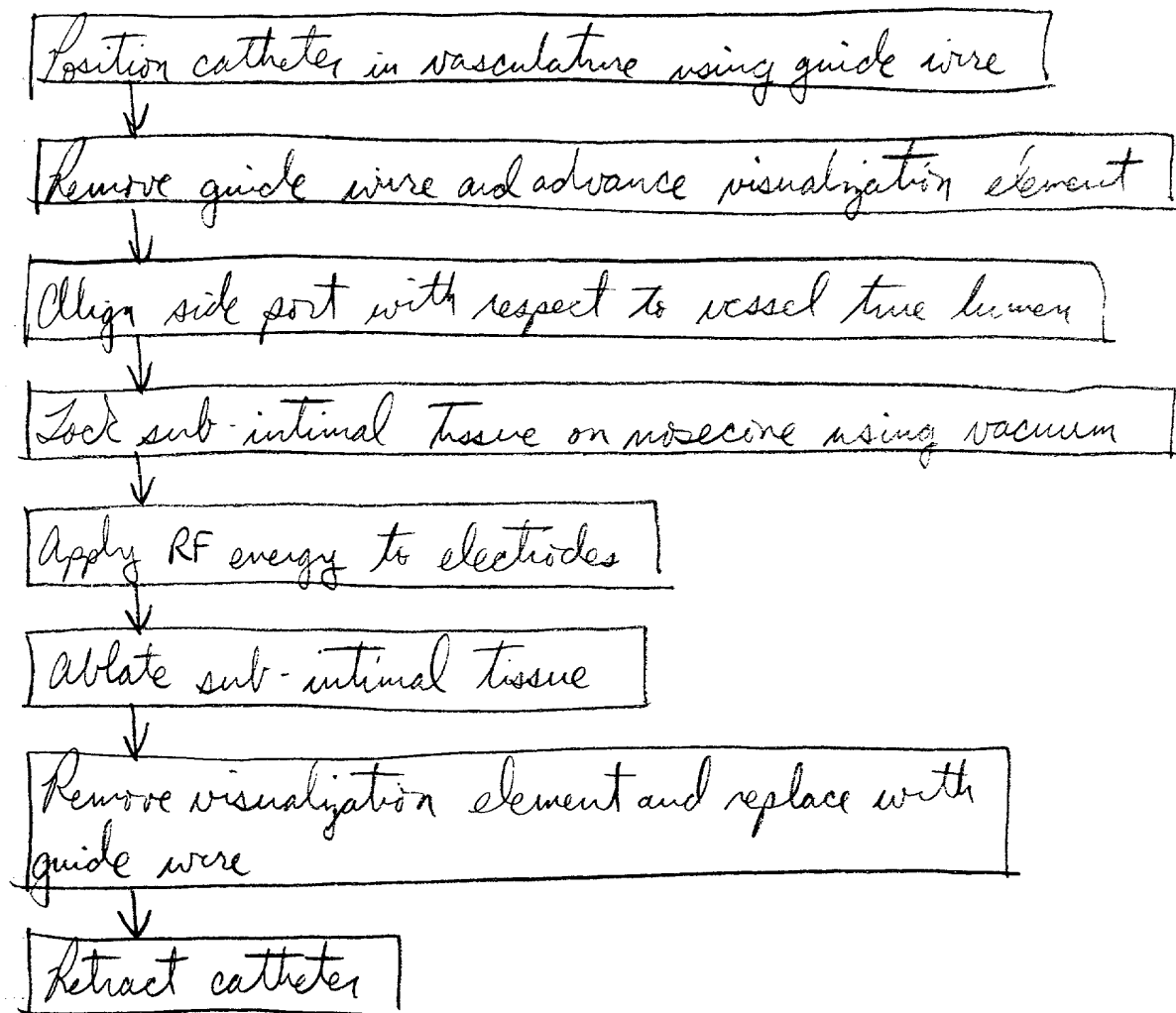


FIGURE 42

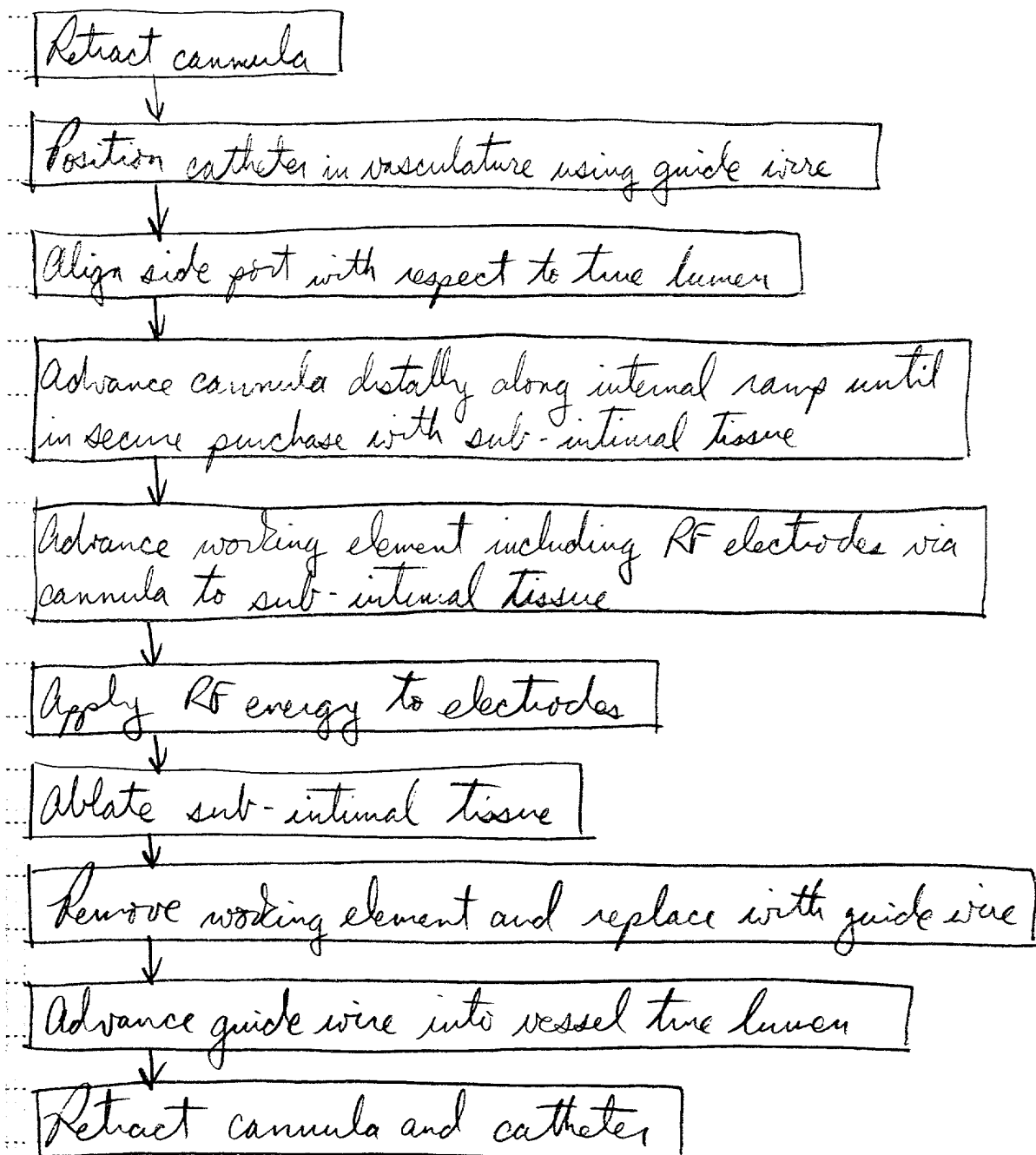


FIGURE 43

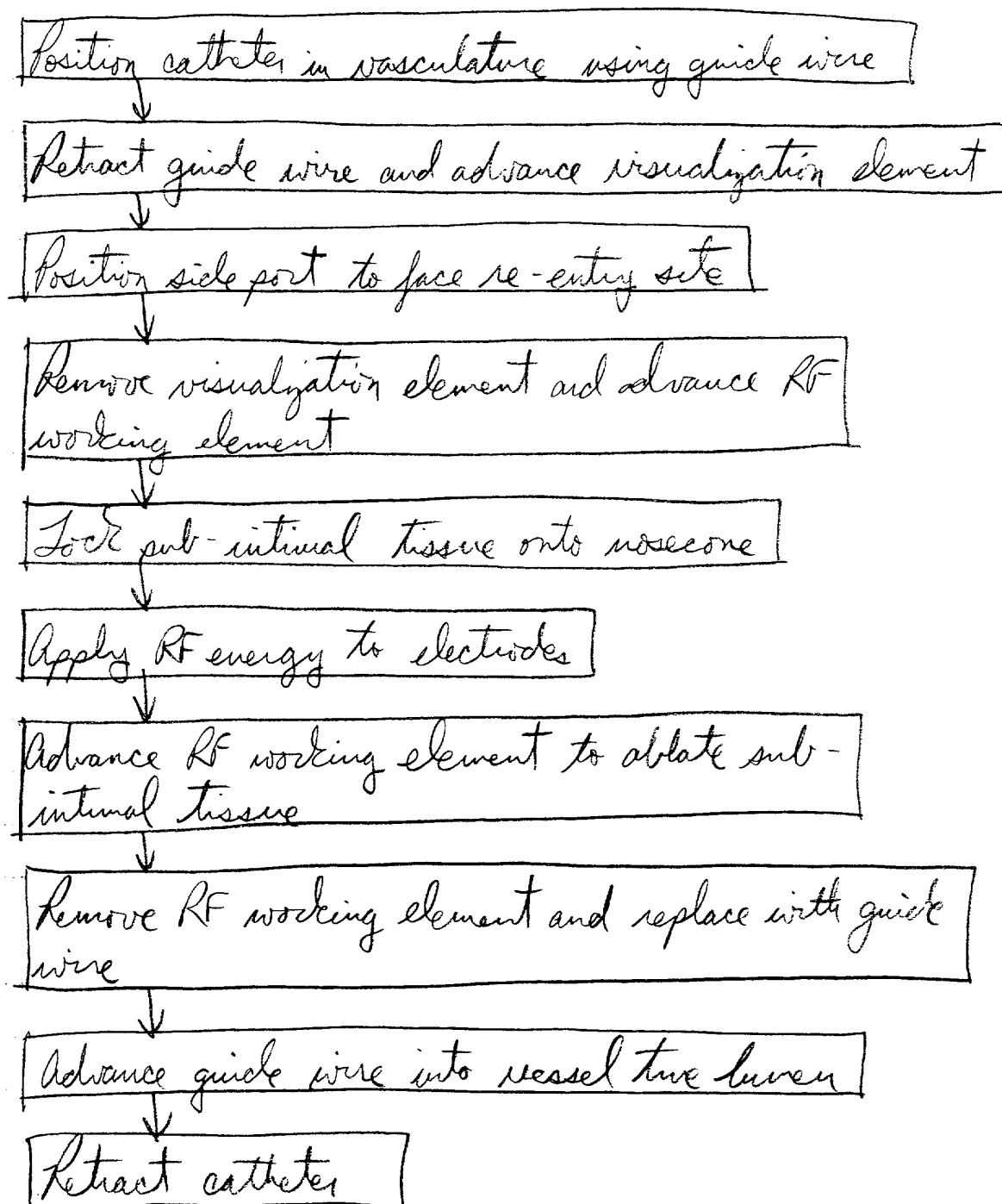


FIGURE 44

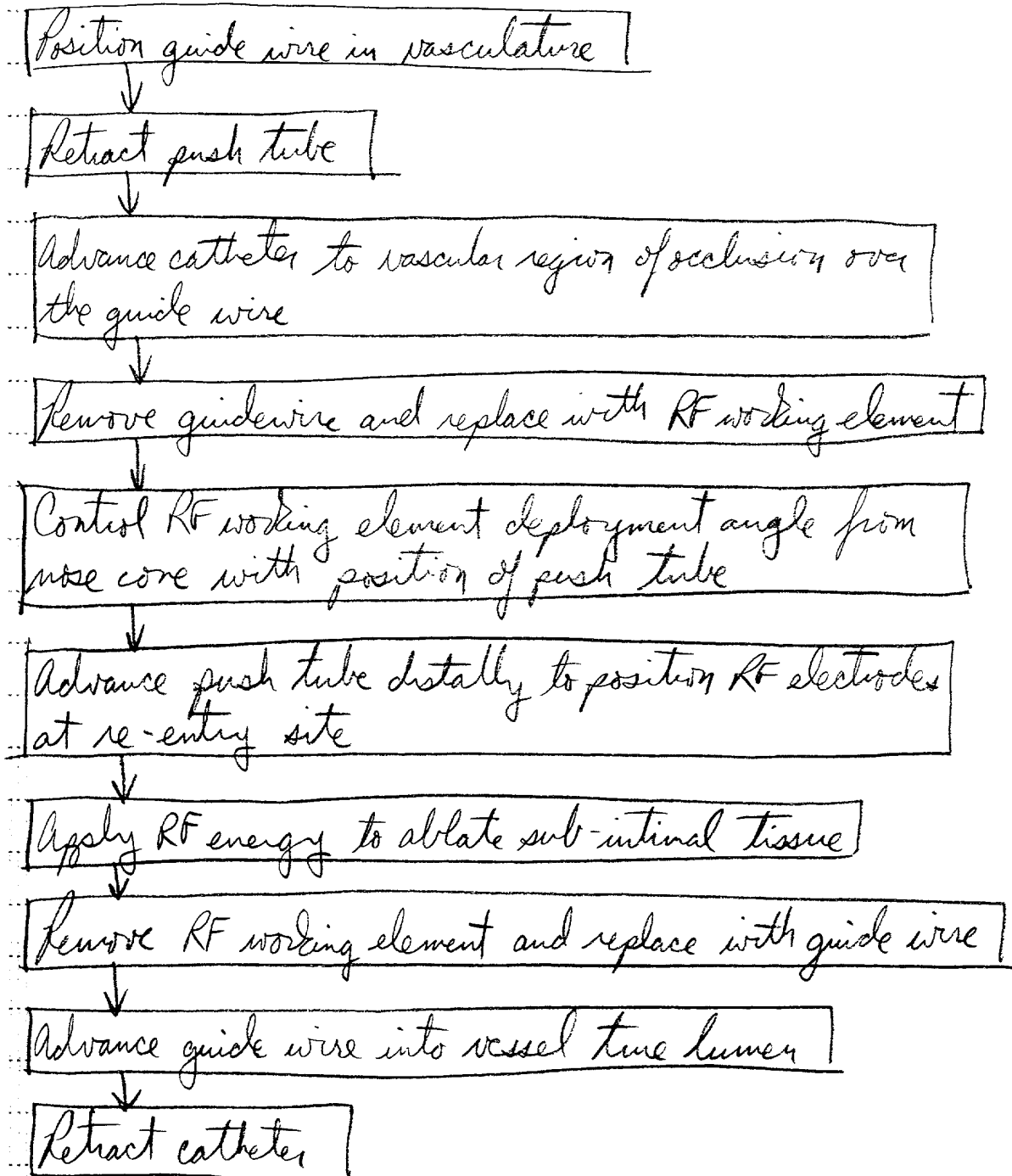


FIGURE 45



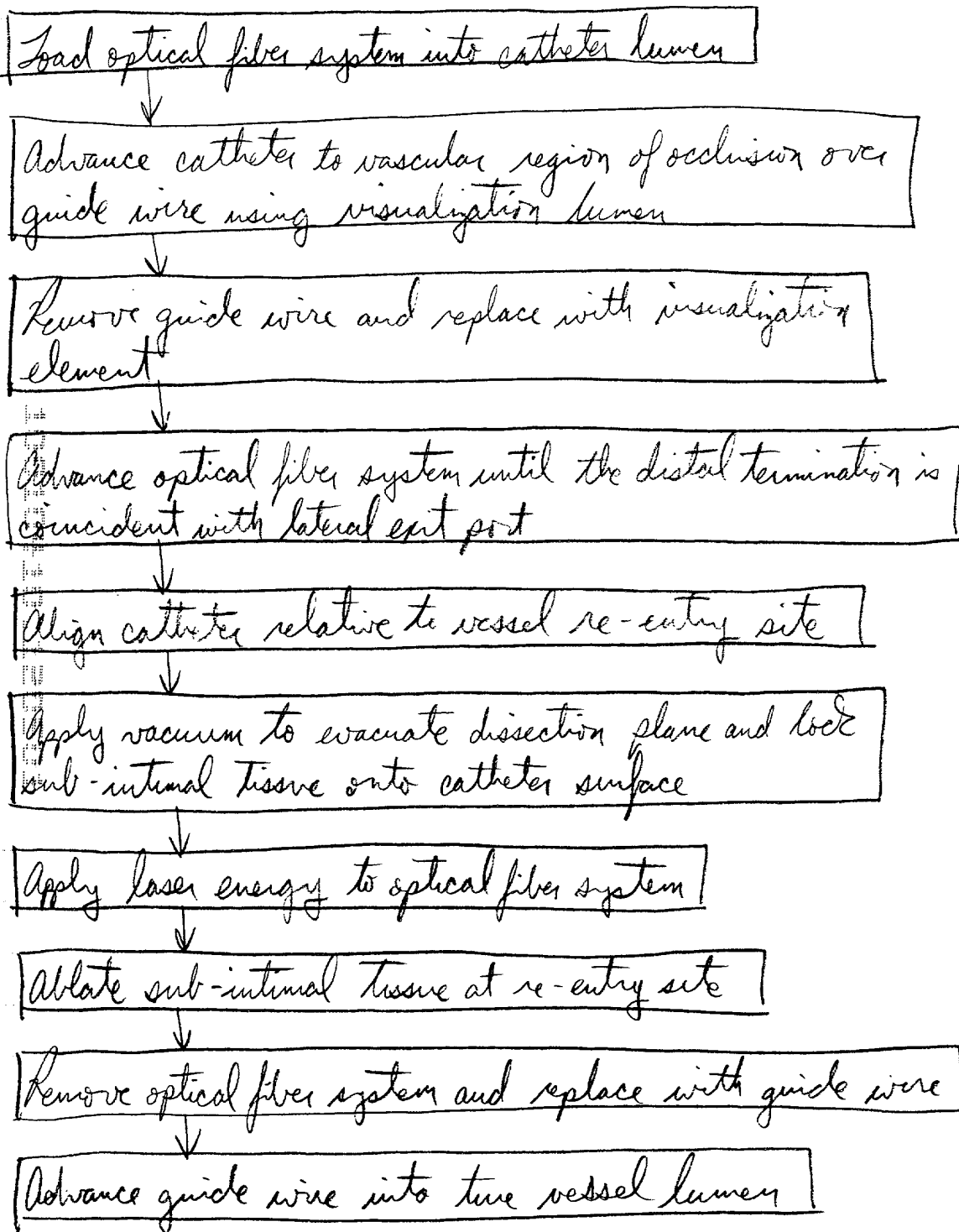


FIGURE 46

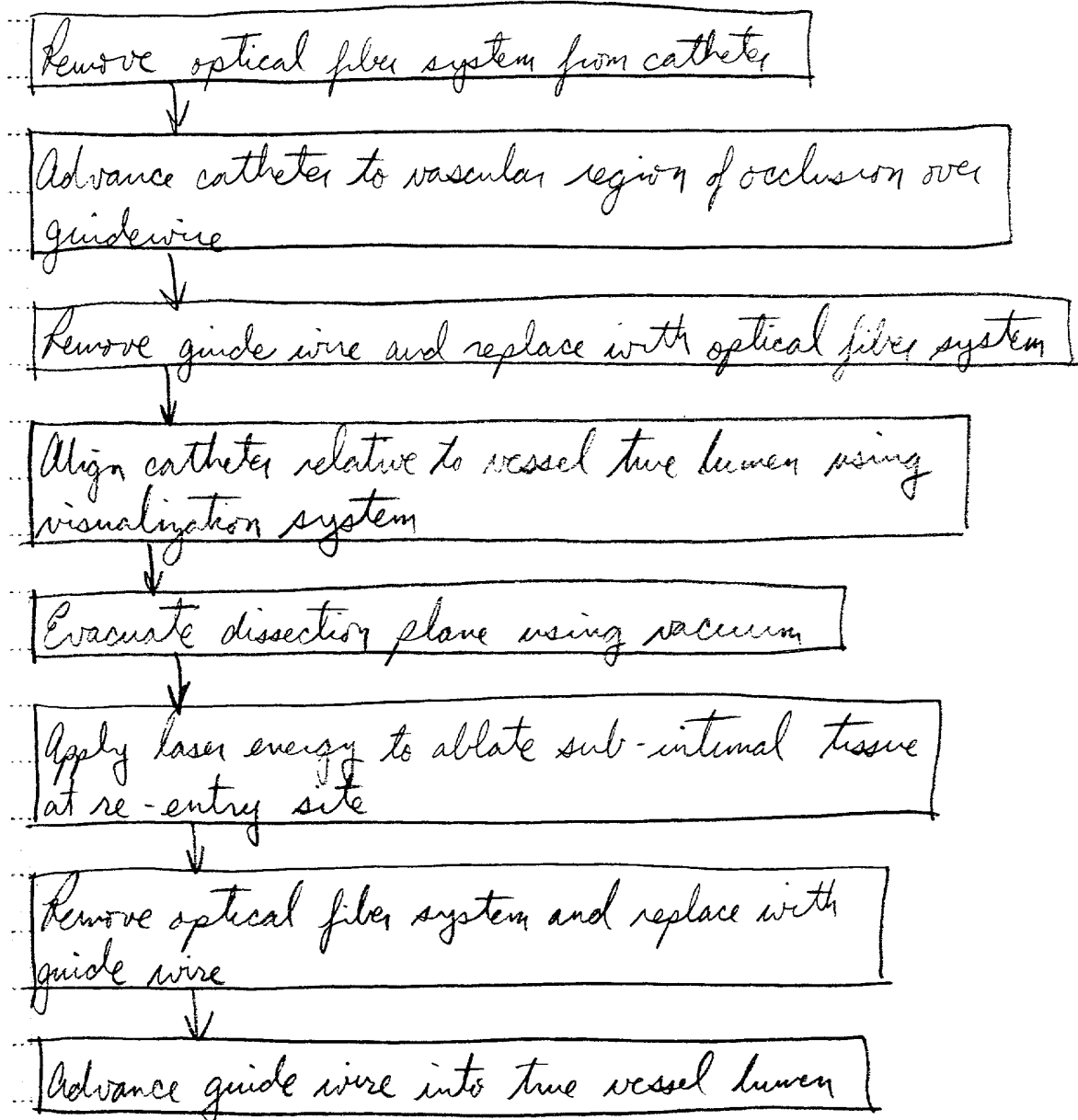


FIGURE 47

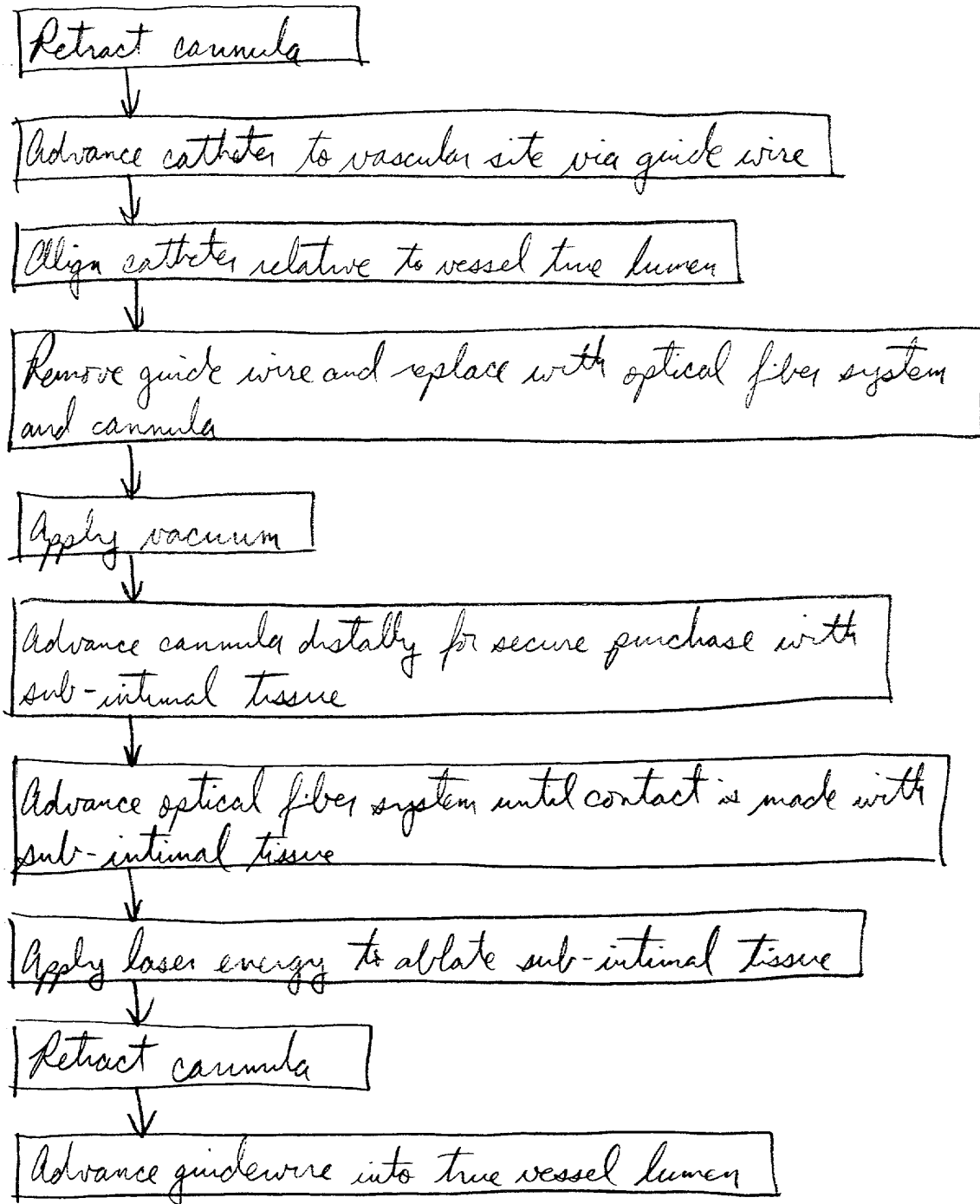


FIGURE 48

Advance catheter to vascular site via guide wire



Align catheter relative to vessel true lumen



Remove guide wire and replace with optical fiber system



Apply vacuum



Advance optical fiber system through nosecone and into contact with sub-intimal tissue



Apply laser energy to ablate sub-intimal tissue



Remove optical fiber system and replace with guidewire



Advance guide wire into true vessel lumen



Retract catheter

FIGURE 49

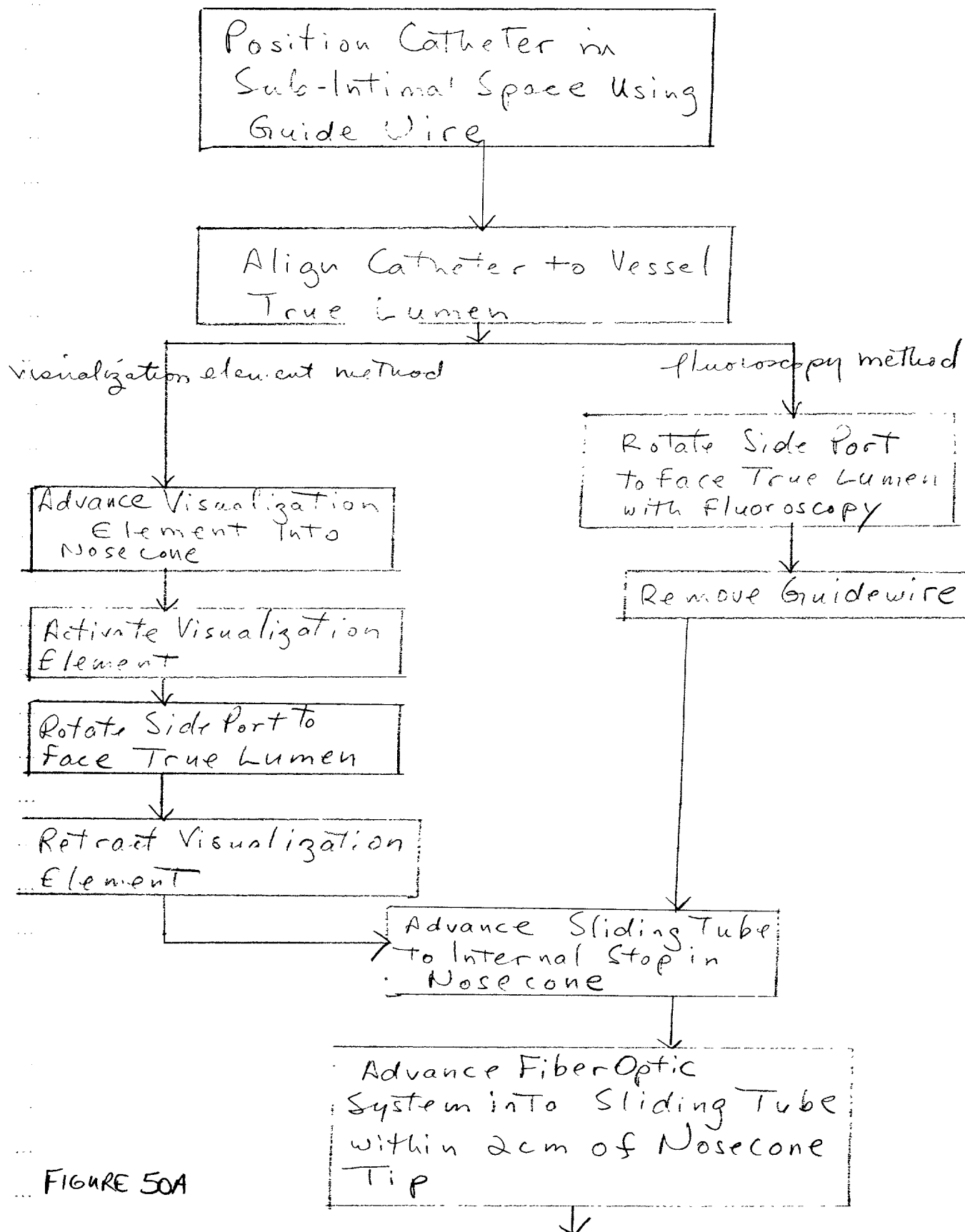


FIGURE 50A

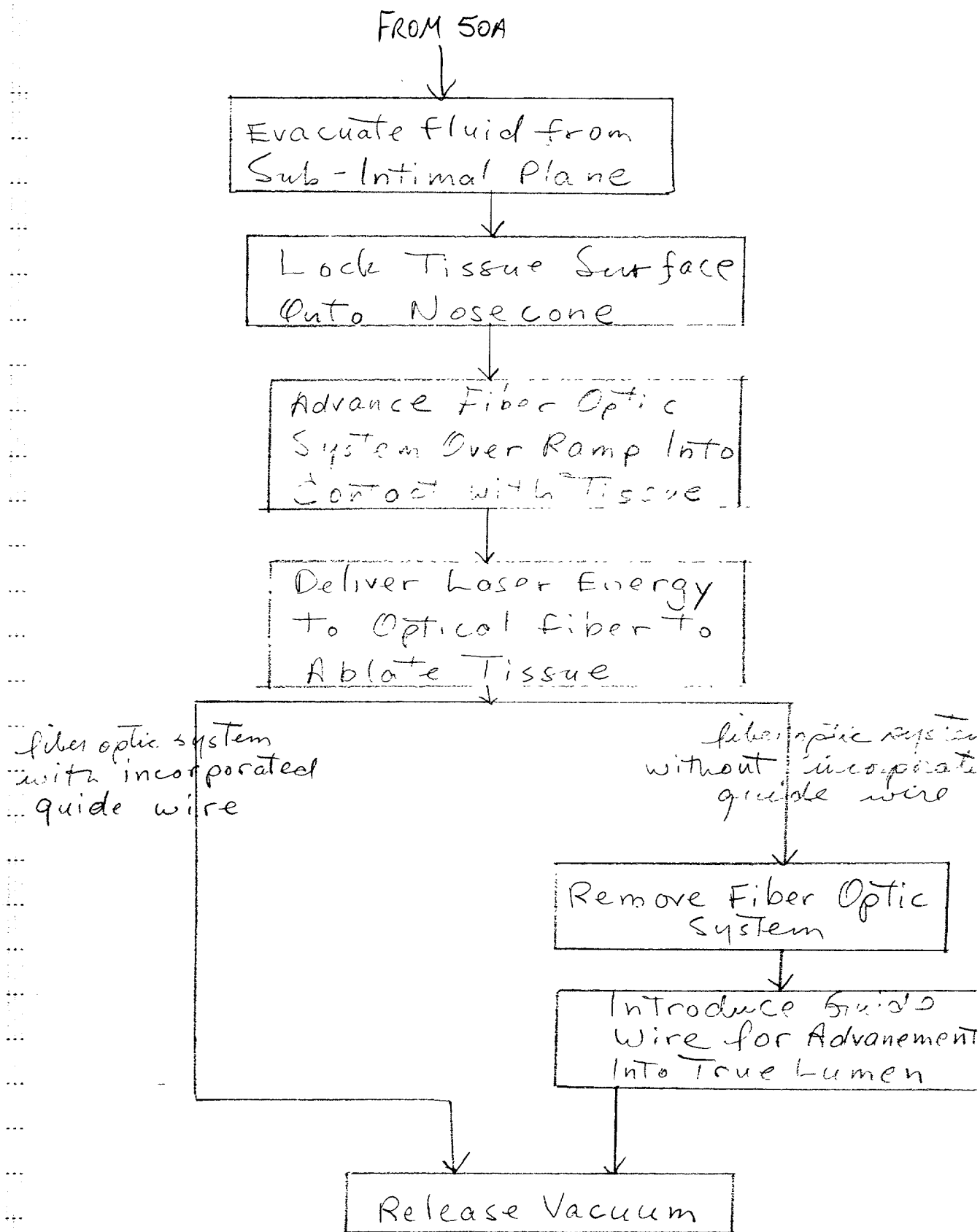


FIGURE 50B

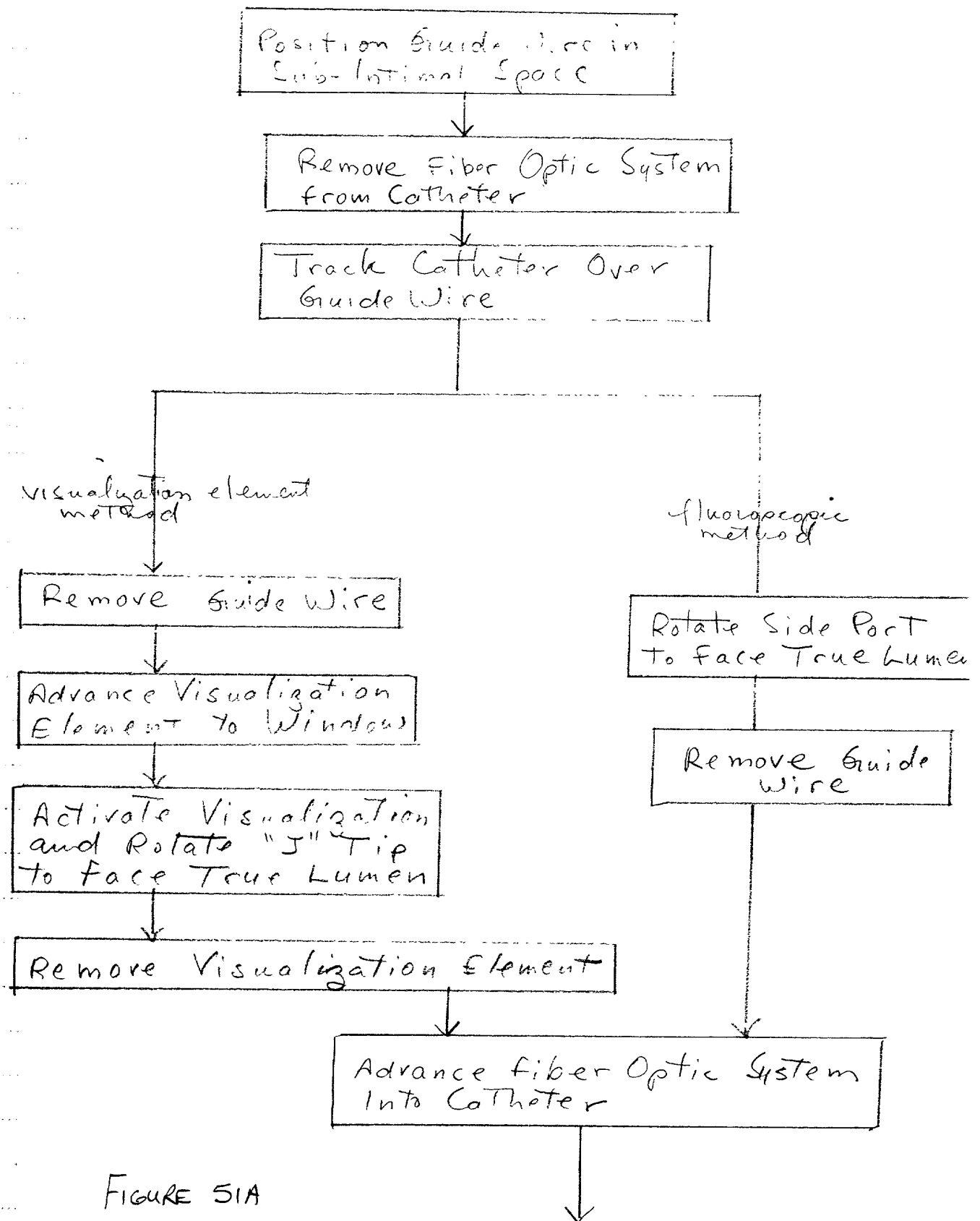


FIGURE 51A

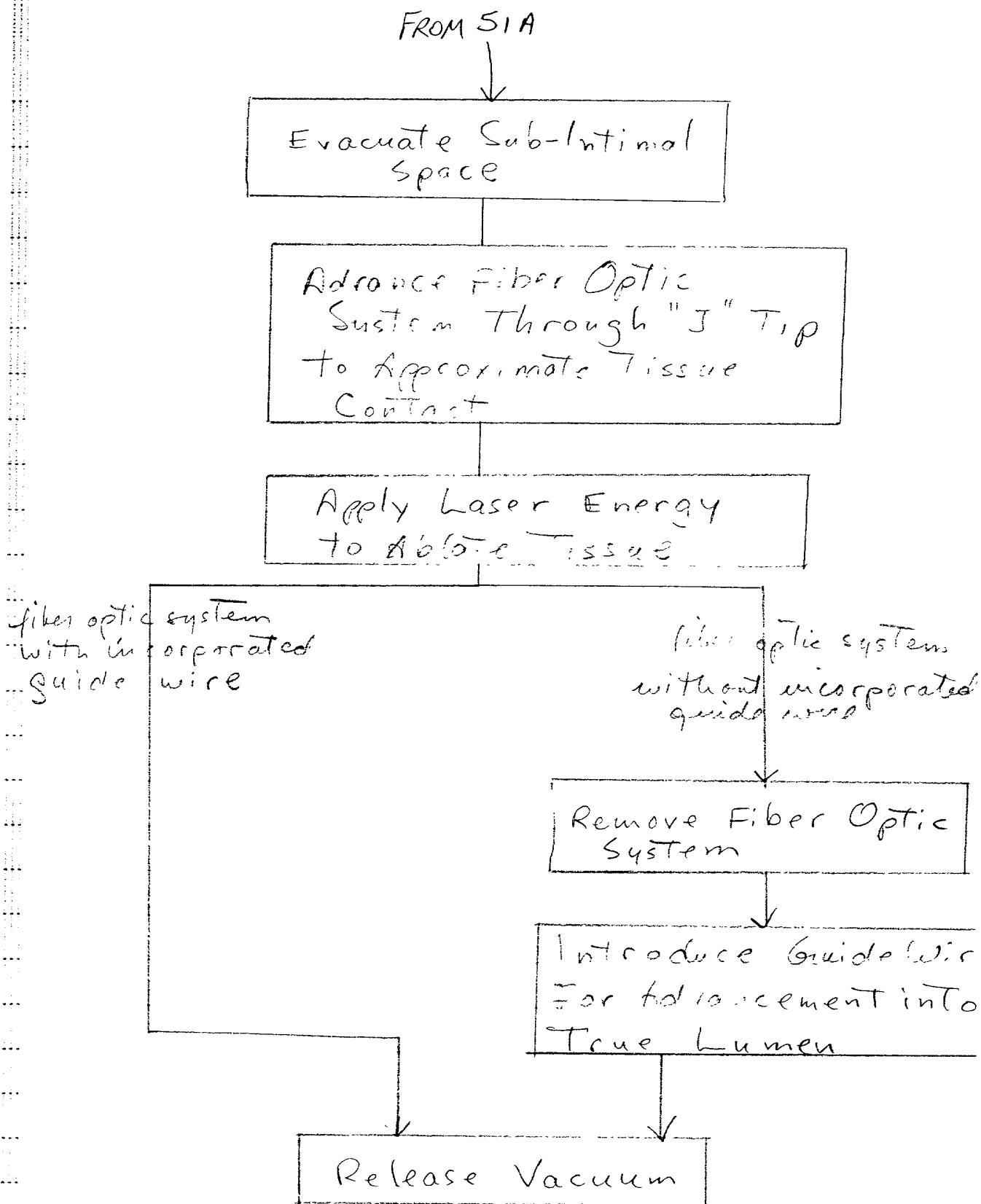


FIGURE 51B



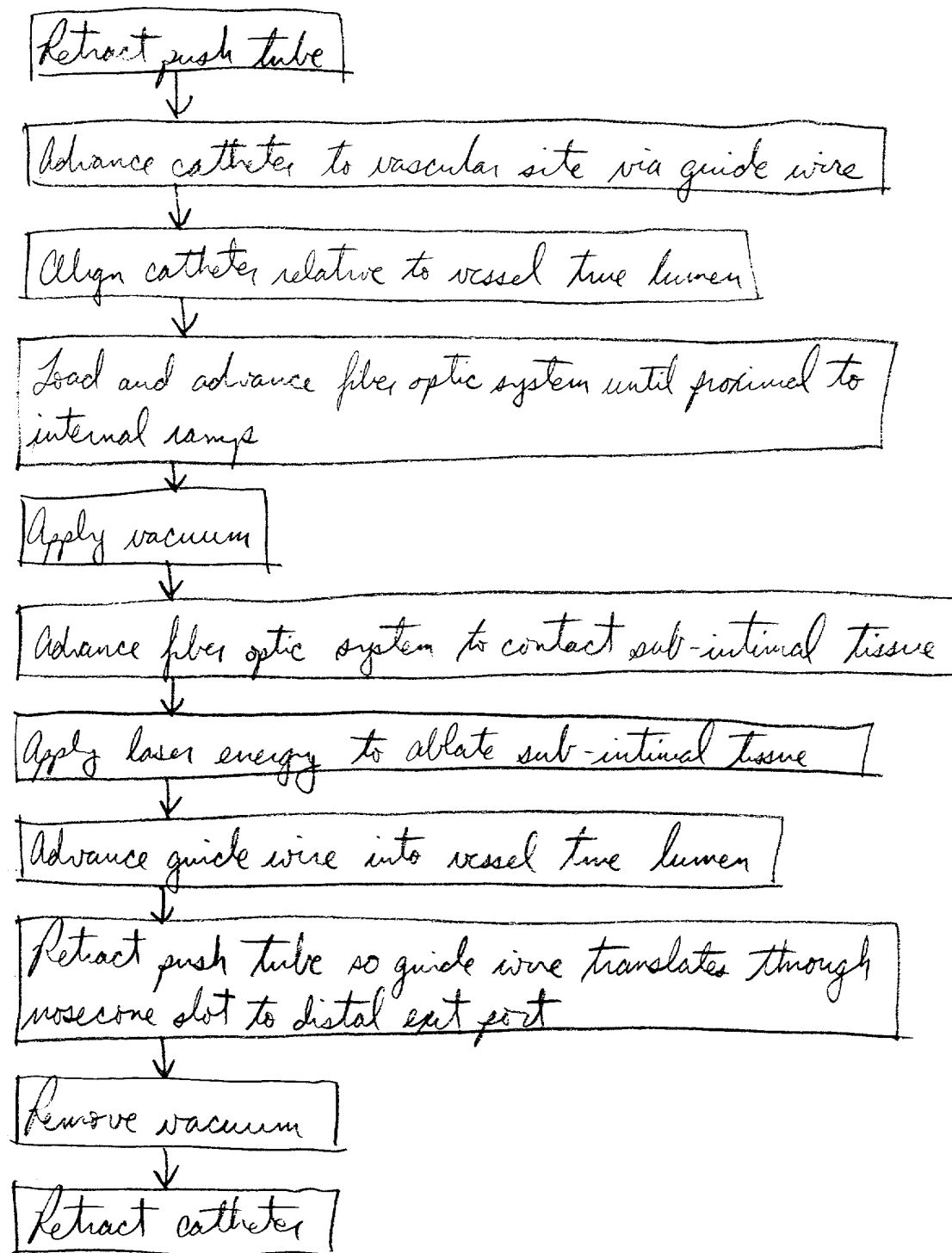


FIGURE 52